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CenterWatch Weekly

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June 29, 2020

CenterWatch Holiday Notification

In observance of Independence Day in the U.S., *CenterWatch Weekly* will not be published Monday, July 6. The next issue will be published Monday, July 13.

Remote Monitoring, Other Pandemic Adjustments Have Led to Hike in Site Costs

By James Miessler

The issues posed by the COVID-19 pandemic have led to a roughly 30 percent increase in site costs, with much of the increase stemming from sites being forced to quickly adopt remote monitoring and other measures in response to the crisis, experts say.

The forced adoption of remote monitoring has played a significant part in the rise in site expenses, says Jeannie Magdalena Gatewood, Temple Health Fox Chase Cancer Center's vice president of clinical research strategy. With some sites still using paper methods and having aging or underfunded infrastructures technology-wise, training has been necessary to implement remote monitoring properly.

"There's been teams that … when I attempted to take their pager and replace it with an iPhone, I had to give a 45-minute training class on how to use smartphone technology," she said during a WCG Clinical webinar last week. "This is a real thing and then it's a real cost. Anything that the sponsors can do to assist sites with getting up to speed I think is going to benefit us all."

Gatewood noted that most site budgets were designed for onsite monitoring, not remote monitoring, leading to unplanned funding for the latter.

"Some of these tight budgets, most of them were built for onsite monitoring and not for remote monitoring and where the overall costs may have been less, the

see **Remote Monitoring** on page 6 »

Pandemic Unleashes Momentous Change in Clinical Research

By Martin Berman-Gorvine

More than half of the top 50 pharma sponsors have had to make protocol changes in their ongoing trials since the COVID-19 pandemic began, driving up volume at IRBs and sparking "remarkable growth" in clinical trials over the past three months.

Data collected by the Tufts Center for the Study of Drug Development (CSDD) show that, as of May 20, only 45 percent of the top 50 sponsors were continuing to follow their trials' original protocols; 30 percent were switching to remote and virtual models; and 25 percent were delaying ongoing activity, CSDD Deputy Director Kenneth Getz told attendees at MAGI's Clinical Research Cloud Conference 2020 last week.

"Initially, this growth really came from protocol design changes and pivots through actively enrolling clinical trials that suddenly had to change their operating model in response to the social distancing requirements and the quarantine requirements that the pandemic introduced," Getz said, but that's been followed by a wave of new protocols for trials of COVID-19 treatments and vaccines, with several hundred now in phase 1, 2 or even further along.

That tremendous push to develop new COVID-19-specific treatments and vaccines has also led to "the rapid relative growth of collaborative sharing co-development arrangements," Getz said.

see **Pandemic Unleashes** on page 7 »

COVID-19 Update

COVID-19 Drug Research Roundup

COVID-19 Vaccines:

Sanofi's CEO Paul Hudson announced that the company's recombinant vaccine, which is using an adjuvant developed by GlaxoSmithKline, is expected to enter a phase 1/2 study in September, faster than originally anticipated. Hudson said that the drugmaker's vaccine candidate could receive approval by the first half of next year.

Chinese biotech **Clover Biopharmaceuticals** has dosed the first participants in a phase 1 trial of its coronavirus vaccine candidate. The Australian study, which is expected to enroll 150 patients, is also evaluating adjuvants from its research partners, Dynavax and GlaxosmithKline. Each dose level will be evaluated with and without the adjuvants. The company expects preliminary results to come out in August and hopes to start an international phase 2/3 trial by the end of the year.

Avalon GloboCare has formed a partnership with Vienna, Austria's **University of Natural Resources and Life Sciences** (BOKU) to develop a COVID-19 vaccine that can be taken intranasally or orally rather than by injection. The two have already begun development of the S-layer protein-based vaccine candidate. It is anticipated to both lessen the severity of COVID-19 infection, preventing more severe respiratory inflammation and organ damage, and help patients build an immunity to the virus.

Imperial College London has dosed the first participant in a phase 1 trial of its RNA-based COVID-19 vaccine candidate. The trial will evaluate the safety of the vaccine and determine optimal dosage. In its initial stage, it will vaccinate 15 healthy volunteers, beginning with a low dose and rising to higher doses for subsequent volunteers. Overall, the college plans to enroll 300 healthy participants over the coming weeks and to start larger trials later this year.

COVID-19 Therapeutics:

Gilead Sciences has gotten the greenlight from the FDA to launch a phase 1 trial of an inhaled version of its antiviral remdesivir for earlier treatment of COVID-19 patients. The drugmaker said it plans to begin trials in August.

The **National Institutes of Health** and **Novartis** have ended late-stage hydroxychloroquine trials after growing evidence suggests the drug is not effective as a COVID-19 treatment. The NIH ended both a phase 2 and a phase 3 trial, while Novartis terminated a phase 3 trial.

Fulcrum Therapeutics has started a phase 3 clinical trial of its investigative anti-inflammatory drug losmapimod for treating hospitalized COVID-19 patients. The trial will enroll 400 patients at risk of progressing to critical illness based on their age and elevated systemic inflammation. Preliminary results are expected in the fourth quarter.

FibroGen has begun a phase 2 trial evaluating its monoclonal antibody pamrevlumab as a treatment for hospitalized COVID-19 patients. The trial will take place at multiple centers in the U.S. and assess the drug's effect on blood oxygenation in 130 infected patients.

Ridgeback Biotherapeutics in July will launch a pair of phase 2 studies of its investigational antiviral EIDD-2801 as a potential COVID-19 treatment. The company said the antiviral has already shown safety and promise in phase 1 studies. One study will assess the drug in newly hospitalized patients, while the other will test the drug in newly diagnosed patients who have not been hospitalized.

Ambio Pharmaceuticals will start a phase 1 clinical trial evaluating its investigational pain treatment Ampion (aspartyl-alanyl diketopiperazine) in COVID-19 patients. The company said it believes the nonsteroidal anti-inflammatory drug could help treat inflammation and improve patient outcomes.

Noxopharm, an Australian drug developer, has begun planning a phase 1 trial of its investigational oncology drug Veyonda (NOX66) in Europe to evaluate its potential as a treatment for cytokine storm and septic shock caused by COVID-19 infection.

Berlin Cures said it will start a phase 2/3 COVID-19 trial of its investigational BC 007, a β1-adrenoceptor autoantibody (β1-AAb) neutralizing ssDNA product, in the second half of 2020. The drug was found to be safe and well tolerated in a previous phase 1 study for a cardiac indication, the German biotech said.

The **European Medicines Agency** (EMA)'s Committee for Medicinal Products for Human Use (CHMP) has given its blessing to Gilead Sciences' remdesivir, recommending it for emergency use in treating COVID-19. The committee based its decision on results from the NIH's National Institutes of Allergy and Infectious Diseases (NIAID) remdesivir trial, which showed that COVID-19 patients recovered more quickly on the drug compared to those taking a placebo. Generally, the EMA follows the committee's recommendations.

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Industry Briefs

CBER Plans to Issue COVID-19 Vaccine Guidance in 2020

As the race to develop an effective COVID-19 vaccine by year's end gains momentum, the FDA said it plans to issue a guidance on developing and licensing them.

In a new guidance agenda for 2020, the FDA's Center for Biologics Evaluation and Research (CBER) does not specify a release date or elaborate on the content of the guidance. But the agency has streamlined its guidance development process during the pandemic and can now produce a guidance in as little as two or three weeks, according to CBER's Director Peter Marks.

The center also intends to issue draft guidance this year on gene therapies for neurodegenerative diseases, on gene therapies that incorporate genome editing and on chimeric antigen receptor (CAR) T-cell therapies.

It also expects to issue final guidance on:

- Human gene therapy for hemophilia, retinal disorders and rare diseases;
- Chemistry, manufacturing and control (CMC) information for human gene therapy investigational new drug applications (INDs); and
- Long-term follow-up after administration of gene therapies; and interpreting the sameness of gene therapies under orphan drug regulations.

In addition, CBER said it aims to release guidance on interacting with the FDA on complex and innovative clinical trial designs for drugs and biological products.

Read CBER's full guidance agenda for 2020 here: https://bit.ly/385GNpt.

Advocacy Group Worries European COVID-19 Trials Won't Publish Results

A majority of European clinical trials of COVID-19 drugs are being run by universities and companies who either lack experience or have a poor track record in uploading their results to the EU's trial database, which could lead to wasted research, according to a new report.

The report, issued by the nonprofit research advocacy group TranspariMED, analyzed 118 clinical trials of potential COVID-19 treatments across Europe and found that a majority of them (79) are being conducted by researchers who have never uploaded clinical trial results onto EudraCT, the EU's clinical trials database.

Of those, 39 are being run by sponsors who have violated the EU's trial transparency regulations in the past, while 40 trials are being run by sponsors that have never completed drug trials before and have never engaged in the uploading process, TranspariMED determined.

Only eight of the remaining 39 trials are being conducted by sponsors that have been fully compliant with the EU's trial transparency rules.

"The large number of COVID-19 trials run by noncompliant and inexperienced trial sponsors poses a threat to the accuracy and utility of data on EudraCT, creating a high risk of research waste," the group said. "This undermines the global search for safe and effective COVID-19 drugs."

The report called for policy action to help address the issue. For example, it called on EU regulators to keep a close eye on COVID-19 trials in their countries and reach out to companies and universities to inform them of their data uploading obligations. They can go further by actively monitoring compliance and providing sponsors with guidance and training materials, the group said.

Additionally, regulators should encourage sponsors to upload their results as soon as possible after their trials conclude, rather than within 12 months as currently required by EU regulations since 2014, and sanction those that neglect to make their trial results public.

Read the full report here: https://bit.ly/3eFJPTy.

Guidance Update

This occasional column provides summaries of newly released FDA guidances of interest to our readers.

Two final guidances the FDA released last week provide an outline for trials of drugs to treat hospital- or community-acquired or ventilator-associated bacterial pneumonia. The guidances point out considerations for trial design, trial population, entry criteria, sampling, dose selection, efficacy endpoints and statistical analysis.

To read the hospital-acquired and ventilator-associated guidances, click here: https://bit.ly/2Ack66s.

To read the community-acquired guidance, click here: https://bit.ly/3g3IoPi.

Lonza Releases Double-Blinded Capsules to Reduce Blinding Issues in Drug Trials

There is a new product available to help overcome blinding challenges in trials that makes it possible to administer a study drug without participants knowing whether they're receiving the investigational product or placebo.

Lonza's Capsugel DBcaps feature an anti-tampering, double-layer design that allows investigators to over-encapsulate drug and placebo products opaquely and offer high visual coverage of what is placed inside. The capsules could improve the cost efficiency of trials, as they reduce the need for companies to produce placebo forms that are identical in size and shape to the candidate drug.

Correction: In the June 22 issue of *CenterWatch Weekly*, the address of LabConnect was listed incorrectly in the MarketWatch column. The correct address is 2304 Silverdale Dr., Suite 100, Johnson City, TN 37601.

Up and Coming

This feature highlights changes in clinical trial organizations' personnel.

Abiomed

Abiomed has announced the appointment of **Charles Simonton** to the role of chief medical officer. Simonton was most recently the chief medical officer at Abbott Vascular.

Adverum Biotechnologies

Laurent Fischer will now lead Adverum Biotechnologies as the company's CEO. Prior to joining Adverum, Fischer was senior vice president and head of the liver therapeutic area at Allergan.

Akcea Therapeutics

Akcea Therapeutics named **Kia Motesharei** senior vice president of business development and corporate strategy. Motesharei was most recently the vice president and global head of licensing and business development for neurology and immunology at Merck.

Bigfoot Biomedical

Former Eli Lilly medical director **Jim Malone** has been named chief medical officer of Bigfoot Biomedical.

BioXcel Therapeutics

Reina Benabou has been named chief development officer at BioXcel Therapeutics. Prior to this new role, Benabou was head of global medical product evaluation at Pfizer.

Cambrex

Thomas Loewald is the new CEO of Cambrex. Previously, Loewald served as president of the flexibles division of ProAmpac.

Cantargia

Susanne Lagerlund has been recruited by Cantargia to assume the role of vice president of regulatory affairs. Most recently, Lagerlund was director of R&D integration at LEO Pharma. **Peter Madsen**, former chemistry, manufacturing and controls (CMC) biologics project director at Lundbeck, has been appointed by Cantargia to the position of vice president of CMC.

Catalyst Biosciences

Charles Democko has been named senior vice president of regulatory affairs at Catalyst Biosciences. Most recently, Democko served as the lead for CytomX's regulatory affairs and quality.

Chimerix

Chimerix has appointed **Allen Melemed** to the role of chief medical officer. Formerly, Melemed served as distinguished medical fellow and senior director of regulatory affairs oncology of North America at Eli Lilly.

COMPASS Pathways

Mental healthcare company COMPASS Pathways has appointed **Trevor Mill** to the role of chief development officer. Mill was most recently senior vice president of global safety and regulatory sciences at Biogen.

Epsilen Bio

Julia Berretta, current CEO of Genespire, has been appointed CEO of Milan-based startup Epsilen Bio.

FibroGen

Thane Wettig has been appointed chief commercial officer of FibroGen. Wettig was most recently chief commercial officer and metabolic franchise head at Intarcia Therapeutics.

Healx

Meri Williams has been named chief technology officer of Healx. Williams was chief technology officer at Monzo prior to this appointment.

JCR Pharmaceuticals

Hiroyuki Sonoda, former corporate officer executive director and research planning at JCR Pharmaceuticals, has assumed the roles of senior executive director and head of research and development division, executive director of research division and director of drug discovery research.

Marinus Pharmaceuticals

Martha Manning has been named vice president, general counsel and secretary at Marinus Pharmaceuticals. Before this role, Manning was executive vice president, general counsel and secretary at Achillion.

Medartis

Medartis has named **Mareike Loch** vice president of Europe, Middle East & Africa (EMEA). Loch was formerly vice president EMEA for the trauma, extremities, foot and ankle, sports medicine and biologics business units at Zimmer Biomet.

miRagen Therapeutics

Lee Rauch, former executive in residence at Columbia Technology Ventures, has been appointed chief operating officer of miRagen Therapeutics.

Nascent Biotech

Navpaul Singh has been hired by Nascent Biotech to be chief medical consultant in charge of research of viral infections, including COVID-19.

Neuraptive Therapeutics

Robert Radie, who most recently served as CEO at Zyla Life Sciences, has been appointed CEO of Neuraptive Therapeutics.

Novavax

Filip Dubovsky has joined Novavax as its chief medical officer. Prior to this appointment, Dubovsky was head of clinical engagement and policy and chief medical officer for clinical affairs at AstraZeneca.

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Up and Coming

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Rallybio

Jackie Schumacher has been appointed to lead regulatory affairs at biopharmaceutical company Rallybio. Previously, Schumacher was vice president of regulatory and quality at Lyndra Therapeutics.

Sangamo Therapeutics

The role of interim head of research at Sangamo Therapeutics will be assumed by **Jason Fontenot**, who had been the company's senior vice president of cell therapy.

Sensei Biotherapeutics

Marie-Louise Fjällskog has been named chief medical officer at Sensei Biotherapeutics. Fjällskog was most recently vice president of clinical development at Merus.

Sygnature Discovery

Paul Overton has been named senior vice president of business development at Sygnature Discovery, a UK-based drug discovery CRO. Most recently, Overton was head of European sales, marketing and key account management at Eurofins.

Vaxart

Andrei Floroiu will now lead Vaxart as its CEO. Floroiu was most recently an executive at Agenus.

X4 Pharmaceuticals

Renato Skerlj has been named chief scientific officer of X4 Pharmaceuticals. Prior to this role, Skerlj was senior vice president of research and development at X4.

XyloCor Therapeutics

Alexander Gaidamaka will now serve as senior vice president of technology, manufacturing and quality at XyloCor Therapeutics. Previously, Gaidamaka was vice president of CMC at AmpliPhi Biosciences.

Zealand Pharma

Frank Sanders will be named U.S. president of peptide-based medicine biotech of Zealand Pharma, a role that will go into effect July 6. Sanders was previously the general manager of the U.S. commercial team at Sage Therapeutics.

Zomedica Pharmaceuticals

Zomedica Pharmaceuticals has appointed **Robert Cohen** to the role of interim CEO. Prior to this appointment, Cohen was president and CEO of EmboMedics.

Features

Remote Monitoring

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investment in that is much more, and that is where we need this strong partnership to get us to where we need to be," she said.

Sites have seen elevated costs in other areas as well as a result of the pandemic, including invoiced items, personnel costs and overhead costs, said Brooke Millman, WCG Clinical's vice president of site contracts and budgets.

"The nonprocedural costs that we're seeing associated with site budgets along with the site costs themselves have increased roughly about 30 percent on average since March," she said.

Costs for invoiced items — such as patient reimbursement for travel and lodging required by more individualized travel — have shot up 50 percent, according to WCG Clinical data, Millman said. For example, the current median rate for patient travel per visit is $50, and that number is anticipated to double as travel options, such as mass transit, become limited due to pandemic constraints, she said.

Personnel costs have risen 20 percent due to increasing costs for site staff time and effort, with study coordinators and principal investigators' time increasing by about 10 percent each, according to requests from WCG-supported sponsors and studies. Additionally, site requests for overhead costs have increased between 5 percent and 10 percent, she said.

The costs incurred by sites will likely continue to change because of the fluid, changing nature of the pandemic, Millman said, noting that average per patient costs had spiked an additional 28 percent since WCG compiled the webinar data, shooting up to roughly $50,000 per patient.

"Something I think we all need to be mindful of is that we all expect that these estimates will fluctuate as we continue to monitor industry trends, and likely will vary heavily by region, country and site as we move through the recovery phase," she said.

"We all expect that these [cost] estimates will fluctuate as we continue to monitor industry trends, and likely will vary heavily by region, country and site as we move through the recovery phase."

—Brooke Millman, WCG Clinical's vice president of site contracts and budgets

Rising costs due to remote monitoring is likely the biggest challenge sites face. George Kourtsounis, Bristol-Myers Squibb (BMS)'s director of clinical trial contracts and grants, said that his company has seen a high number of remote monitoring requests related to setup and trial duration during the crisis.

"The position that I'm seeing across industry is certainly that that can be encapsulated on the site level by either an administrative startup fee or putting it into the individual overhead component," he said.

Sites with budgets designed for traditional monitoring can run into challenges when using remote monitoring, however, as the traditional way requires less time and effort, according to current data, he said.

"We're running into a potential risk in terms of compliance," Kourtsounis said, "because if we're already paying for a budget on the assumption of traditional monitoring and the industry is telling us that remote monitoring is less invasive and less time-consuming, then how can we justify paying in the event of an audit or an additional remote monitoring piece?"

BMS has also seen increased requests for electronic medical record (EMR) agreements during the pandemic, the executive noted. He suggested that as the industry moves toward incorporating more technology into its approaches, it should look at how it handles those types of agreements. That could involve broadening confidentiality provisions or making them more explicit within clinical trial agreements so that EMR agreements are not needed. He added that with increased use of EMRs, sites should keep privacy concerns in mind — especially in the EU where data protection regulations are strong — in addition to IT security concerns.

In addition, a large number of sites have asked for reimbursement for personal protective equipment (PPE). The costs vary widely depending on jurisdiction, availability and supply chain concerns, he said.

Alongside the use of PPE as an added safety measure, sites have been administering COVID-19 tests to protect those involved in their trials from potential infection, another previously unexpected cost that has raised questions about who should pay it. Kourtsounis says it depends on the situation; the sponsor should cover the costs if it's for an adverse event, but protocol-mandated testing should be paid for by sites, he said.

"The principle really that I'm seeing across industry is if it's being required for everyone that walks through the door and it's not specific to research, then that should be … borne by the site because, whether they were participating in research or not, those are the security protocols and procedures that the sites would need to enforce," he said.

Kourtsounis said that while the industry may need some more time getting settled in to the new landscape carved out by the pandemic, overall, he thinks it will come out better than before.

"I think what we're seeing a lot with the study coordinators is everyone is adjusting to a new way of working," he said. "Things are just going to take a little bit longer period of time, even though downstream, I believe that we're going to be more efficient, more transparent as an industry."

Features

Pandemic Unleashes

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The total number of co-development arrangements announced publicly in the past four months is greater than the total in the three years before that, he said, according to the CSDD's analysis. Of the 50 research sponsors examined, 34 percent were engaged in independent development of treatments and vaccines and 42 percent were engaged in collaborative development as of March 30, rising to 46 percent and 56 percent, respectively, as of May 8.

The public is putting a lot of hope in the ability of clinical researchers to fight COVID-19. Getz said that 60 percent expect a vaccine in less than one year and 33 percent in one to two years, with only 7 percent thinking it will take more than two years, according to an international survey of 500 people conducted at the end of April by the Center for Information and Study on Clinical Research Participation. The more rapid timelines may not be realistic, he noted. And on the downside of public opinion, only 55 percent said they would be somewhat or very willing to participate in clinical trials, compared to a steady level of around 85 percent pre-pandemic. Nine in 10 subjects actually participating in clinical trials at that point reported changes in the process, with 26 percent reporting that their trials had been suspended.

"The pandemic has been a catalyst in forcing new clinical trial execution models to go mainstream."

—Kenneth Getz, deputy director of the Tufts Center for the Study of Drug Development

"There are four key takeaways from the pandemic," according to Getz:

- "The pandemic has been a catalyst in forcing new clinical trial execution models to go mainstream, and they will be part of a mix of options that we will need to be able to offer our volunteers on a long-term basis";
- The pandemic is ushering in a new era of proactive regulatory encouragement and involvement;
- The response to the current pandemic and efforts to anticipate future pandemics are leading to "structural site landscape changes"; and
- The pandemic has exposed the new work-from-home model, which will lead to further developments in technology and data gathering methods.

Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
COVID-19 Trials and Actions				
Clover Biopharma GlaxoSmithKline	COVID-19 vaccine	COVID-19	initiation of phase 1 trial	cloverbiopharma.com gsk.com
Theravance Biopharma	TD-0903	hospitalized patients with acute lung injury caused by COVID-19.	dosing of first patient in phase 2 trial	theravance.com
Fulcrum Therapeutics	losmapimod	higher-risk hospitalized adults with COVID-19	initiation of phase 3 trial	fulcrumtx.com
Ridgeback Biotherapeutics	EIDD-2801	Study 2003: recently symptomatic, newly diagnosed nonhospitalized patients. Study 2004: hospitalized patients with COVID-19	initiation of two phase 3 trials	ridgebackbio.com
Ampio Pharmaceutical	intravenous Ampion	SARS-CoV-2 virus	IND approved by the FDA	ampiopharma.com
NeuroRx Relief Therapeutics	RLF-100 (Aviptadil)	acute lung injury/acute respiratory distress syndrome associated with COVID-19	Fast Track designation granted by the FDA	neurorxpharma.com reliefftherapeutics.com
OmniPathology	Omni-COVID-19 Assay PCR test	detection of SARS-CoV-2	Emergency Use Authorization (EUA) granted by the FDA	omnipathology.com
Gencurix	GenePro SARS-CoV-2 RT-PCR Test	detection of SARS-CoV-2	EUA granted by the FDA	gencurix.com
Other Trials and Actions				
Allied Corp. MGC Pharmaceutical	proprietary cannabis-derived drug candidate	post-traumatic stress disorder	initiation of phase 1 trial	allied.health mgcpharma.com.au
ABM Therapeutics	ABM-1310	BRAF mutant advanced solid tumor and BRAF mutant patients with brain metastases	dosing of first patient in phase 1 trial	abmtx.com
Aduro Biotech	BION-1301	IgA nephropathy	dosing of first patient in phase 1 trial	aduro.com
Alpine Immune Sciences	ALPN 202	advanced malignancies	dosing of first patient in phase 1 trial	alpineimmunesciences.com
Heat Biologics/ Pelican Therapeutics	PTX-35	advanced refractory solid tumors	dosing of first patient in phase 1 trial	heatbio.com
Revolution Medicines	RMC-4630 (SAR442720) in combination with Keytruda (pembrolizumab)	advanced malignancies	dosing of first patient in phase 1 trial	revmed.com
Seattle Genetics	SEA-TGT/ SGN-TGT	solid tumors and lymphomas	dosing of first patient in phase 1 trial	seattlegenetics.com
Seattle Genetics	SGN-B6A	solid tumors	dosing of first patient in phase 1 trial	seattlegenetics.com
Springworks Therapeutics	nirogacestat and belantamab mafodotin	relapsed or refractory multiple myeloma	dosing of first patient in phase 1b trial	springworkstx.com

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Drug & Device Pipeline News

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Company	Drug/Device	Medical Condition	Status	Sponsor Contact
BioInvent	BI-1206 in combination with Keytruda	solid tumors	enrollment of first patient in phase 1/2 trial	bioinvent.com
Grid Therapeutics	GT103	refractory NSCLC	dosing of first patient in phase 1/2 trial	gridtherapeutics.com
NeoImmuneTech	NT-I7 (efineptakin alfa) in combination with Keytruda	relapsed/refractory advanced solid tumors	dosing of first patient in phase 1/2 trial	neoimmunetech.com
Tarsius Pharma	TRS01	active anterior noninfectious uveitis	completion of patient enrollment in phase 1/2 trial	tarsiuspharma.com
Aerpio Therapeutics	topical formulation of razuprotafib	elevated intraocular pressure associated with open angle glaucoma or ocular hypertension	initiation of phase 2 trial	aerpio.com
Oncolytics Biotech	pelareorep-based combination therapies	HR+/HER2- metastatic breast cancer	dosing of first patient in phase 2 trial	oncolyticsbiotech.com
Reistone Biopharma	SHR0302	moderate and severe Alopecia Areata	dosing of first patient in phase 2 trial	reistonebio.com
Arcutis Pharma	roflumilast foam	seborrheic dermatitis	completion of patient enrollment in phase 2 trial	arcutis.com
Ziopharm	Ad-RTS-hIL-12 with veledimex in combination with Libtayo (cemiplimab-rwlc)	recurrent or progressive glioblastoma	completion of patient enrollment in phase 2 trial	ziopharm.com
Aurinia Pharma	voclosporin ophthalmic solution	dry eye syndrome	completion of patient enrollment in phase 2/3 trial	auriniapharma.com
Mitsubishi Tanabe Pharma Development America	MT-7117 (dersimelagon)	erythropoietic protoporphyria (EPP) or X-linked protoporphyria (XLP)	initiation of phase 3 trial	mt-pharma-america.com
Pfizer	20vPnC vaccine	pneumococcal disease	initiation of two phase 3 trials	pfizer.com
Pfizer	RSVpreF vaccine	respiratory syncytial virus	initiation of phase 3 trial	pfizer.com
Pfizer	MenABCWY vaccine	meningitis	initiation of phase 3 trial	pfizer.com
Sanofi	SAR442168	relapsing multiple sclerosis	first patient enrolled in phase 3 trial	sanofi.com
Soligenix	SGX942 (dusquetide)	oral mucositis in head and neck cancer patients	completion of patient enrollment in phase 3 trial	soligenix.com
Altimmune	HepTcell	chronic hepatitis B	IND approved by the FDA	altimmune.com
HemoShear Therapeutic	HST5040	methylmalonic acidemia and propionic acidemia	IND approved by the FDA	hemoshear.com
Novaremed AG	NRD135S.E1	painful diabetic peripheral neuropathy	IND approved by the FDA	novaremed.com
Polynoma	seviprotimut-L	adjuvant treatment of stage IIB/IIC melanoma patients post-resection	Fast Track designation granted by the FDA	polynoma.com

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Drug & Device Pipeline News

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Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Viracta Therapeutics	nanatinostat and valganciclovir combination treatment	T-cell lymphoma	Orphan Drug designation granted by the FDA	viracta.com
TFF Pharmaceutical	tacrolimus inhalation powder	prophylaxis of lung allograft rejection	Orphan Drug designation granted by the FDA	tffpharma.com
IMARA	IMR-687	beta-thalassemia	Orphan Drug designation granted by the FDA	imaratx.com
Dicerna Pharmaceutical	nedosiran	primary hyperoxaluria	Rare Pediatric Disease designation granted by the FDA	dicerna.com
Ovid Pharmaceutical	OV101 (gaboxadol)	Angelman syndrome	Rare Pediatric Disease designation granted by the FDA	ovidrx.com
preCARDIA	preCARDIA catheter system	acutely decompensated heart failure	Breakthrough Device designation granted by the FDA	precardia.com
Karyopharm Therapeutics	Xpovio (selinexor)	relapsed or refractory diffuse large B-cell lymphoma	approved by the FDA	karyopharm.com
Epizyme	Tazverik (tazemetostat)	adults with relapsed or refractory follicular lymphoma (FL) with EZH2+ tumors and who have received at least two prior systemic therapies and adults with relapsed or refractory FL with no satisfactory alternative treatment options	approved by the FDA for two new indications	epizyme.com
Merck	Keytruda (pembrolizumab)	recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation	approved by the FDA for two new indications	merck.com
Evoke Pharma	Gimoti (metoclopramide) nasal spray	adults with acute and recurrent diabetic gastroparesis	approved by the FDA	evokepharma.com
Regeneron Sanofi	Dupixent (dupilumab) single-dose pre-filled pen	atopic dermatitis, asthma and chronic rhinosinusitis with nasal polyposis	approved by the FDA for new formulation	regeneron.com sanofi.com
Ultragenyx Kyowa Kirin	Crysvita (burosumab)	FGF23-related tumor-induced osteomalacia in patients <2 years of age	approved by the FDA	ultragenyx.com kyowakirin.com