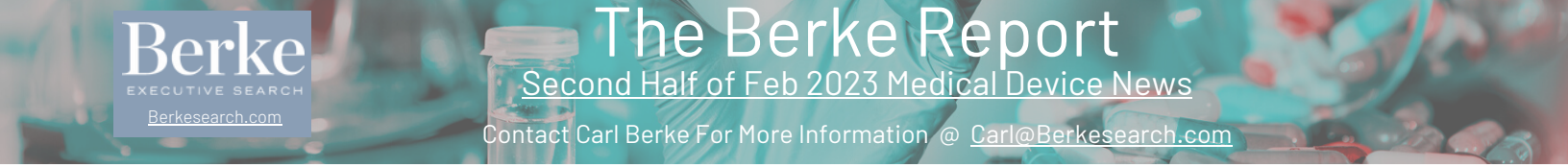

- 02.28.23 - ReCor Medical announces more positive study results for its renal denervation system (massdevice)
  - ReCor Medical announced today that its Paradise ultrasound renal denervation (uRDN) system successfully reduced blood pressure in a study. Palo Alto, California-based ReCor published primary endpoint results from its Radiance II trial in the Journal of the American Medical Association (JAMA). Results showed success for Paradise in reducing blood pressure compared to sham. Additionally, pooled analysis from multiple studies showed consistent blood pressure lowering. This took effect across a range of hypertension, including mild to moderate and resistant hypertension.
- 02.28.23 - Data backs Abbott Navitor, Amulet heart implants (massdevice)
  - Results from the Navitor study supported recent FDA approval for the transcatheter aortic valve implantation (TAVI) system. The FDA last month approved the system for treating severe, symptomatic aortic stenosis in those at high or greater risk for open-heart surgery. Data also demonstrated the benefits of the Amplatzer Amulet left atrial appendage (LAA) occluder, according to a news release. It offers immediate and complete closure of the LAA for patients with AFib at risk of stroke.
- 02.27.23 - Median Technologies Announces Completion of the Q-Submission Phase with the FDA for its iBiopsy® Lung Cancer Screening CADe/CADx Software as Medical Device (Biospace)
  - The Q-submission phase was initiated on May 2, 2022 with the FDA. The Q-submission phase aims at clarifying and implementing the FDA's expectations on key topics including pivotal study protocols. Further to the Q-submission phase completion, Median's iBiopsy® LCS CADe/CADx SaMD pivotal study protocols are now finalized and ready for study execution. Median Technologies aims at starting the execution of the iBiopsy® LCS CADe/CADx SaMD pivotal studies by the end of Q2, 2023 and obtaining 510(k) clearance in the first half of 2024.
- 02.23.23 - Research Park at Florida Atlantic UniversityR Based FloSpine Receives FDA Clearance for 3D Printed Titanium Cervical Implant (infomednews)
  - Together with FloSpine, LLC, the Research Park at Florida Atlantic University® is pleased to announce that FloSpine has achieved 510(k) clearance for its first 3D Printed Titanium Ti-Largo™ Cervical Interbody Cage System from the Food and Drug Administration (FDA). The Ti-Largo™ Cervical Interbody Cage System is used to support the spine after a cervical collapse or damaged disc has been removed and is replaced with the Ti-Largo implant to restore the height. All Ti-Largo implants utilize titanium additive manufacturing (3D printing) and a patent-pending design to create a highly porous surface structure that allows for bone ingrowth to the implant surfaces, maximizing strength, stability and biologic fixation.
- 02.24.23 - Olympus mounts $370M bid to acquire GI stent maker Taewoong Medical (fiercebiotech)
  - At the end of 2019, Olympus outlined an updated game plan for its medical device business, directing its focus toward gastrointestinal, urological and respiratory care, complete with increased investment in endoscopy-related devices—and especially in single-use endoscopy tools—to better treat diseases in those areas. A year later, the devicemaker is still plowing ahead with that plan, as evidenced by its latest acquisition. Olympus is offering up a total of $370 million in cash to purchase Taewoong Medical, according to a Friday announcement. Taewoong is the South Korea-based maker of a variety of endoscopic devices for gastrointestinal procedures. In the announcement, Olympus singled out its broad slate of metallic GI stents, which are used in minimally invasive procedures to open up a biliary tract, esophagus, colon or duodenum that has been blocked or narrowed due to cancer or another condition in the digestive system.
- 02.23.23 - Medtronic relaunches pulmonary valve that was subject of recall (medtechdevice)
  - Medtronic said it is relaunching its Harmony transcatheter pulmonary valve that offers a minimally invasive alternative to open-heart surgery for treating patients with severe leakage. The valve replacement system was granted FDA approval two years ago, but the company recalled the device last year after six reported cases in which the bond holding the capsule at the end of the delivery catheter broke. After correcting the problem, Medtronic now has FDA approval to bring the valve back to market, a move that will help speed revenue growth for the company in its fiscal fourth quarter, CFO Karen Parkhill said last week.
- 02.21.23 - Expanding Innovations, Inc. Announces FDA Approval of X-PAC Expandable Lateral Cage System (Biospace)
  - Expanding Innovations, Inc. Announces FDA Approval of X-PAC Expandable LateraExpanding Innovations, Inc. (EI), a spinal implant company that designs NON-SCREW based expandable cage technology, announced today that the company has received 510(k) clearance from the FDA for the X-PAC Expandable Lateral Cage System (X-PAC LLIF). This approval marks a significant addition to the company's expandable product portfolio which also includes the company's flagship X-PAC Expandable Posterior Cage System (X-PAC TLIF).l Cage System (Biospace)
- 02.16.23 - CurvaFix Launches Smaller-diameter CurvaFix® IM Implant (biospace)
  - CurvaFix, Inc., a developer of medical devices to repair fractures in curved bones, today announced the launch of its smaller-diameter, 7.5mm CurvaFix® IM Implant, designed to simplify surgery and provide strong, stable fixation in small-boned patients. The company will showcase the new 7.5mm intramedullary device, of which over two dozen have already been implanted in patients, at the American Academy of Orthopedic Surgeons (AAOS) 2023 Annual Meeting in Las Vegas, March 7-11 (booth 1223). The company will also highlight the 9.5mm CurvaFix Implant, launched in late 2021, and provide updates from recent U.S. cases.

- 02.24.23 - Pfizer's Paxlovid gets March FDA advisory meeting to discuss full approval (endpts)
  - Pfizer's antiviral drug for Covid-19 is looking to inch closer to full FDA approval, with an agency advisory committee scheduled for March. The meeting is going to be held on March 16 from 9 a.m. to 5 p.m. EST, according to a document in the federal register from the US Department of Health and Human Services. The meeting will focus on whether Paxlovid should be approved to treat mild-to-moderate Covid-19 in adults who are at high risk for the virus' progression to a severe case which can lead to hospitalization or death. Currently the antiviral is approved only on an emergency-use basis.
- 02.22.23 - Amicus Therapeutics Announces Positive Long-Term Data from Phase 3 Open-label Extension Study of AT-GAA in Late-Onset Pompe Disease
  - Meaningful and Durable Responses in Key Endpoints of Six-Minute Walk, Forced Vital Capacity for ERT-Naïve and ERT-Experienced Participants Out to Two Years. Consistent Reduction in Biomarkers Continue to Suggest a Positive Effect on Muscle Tissue; Including Participants who Switched from alglucosidase alfa to AT-GAA in the Open-label Extension. Safety Profile Aligns with Previously Reported Data
- 02.21.23 - Vaxcyte Announces FDA Clearance of Investigational New Drug Application for VAX-24 for the Prevention of Invasive Pneumococcal Disease in Infants (PR)
  - Infant Phase 2 Study Initiation Expected in the Second Quarter of 2023, with Initial Topline Safety, Tolerability and Immunogenicity Data by 2025. Based on Positive Topline VAX-24 Phase 1/2 Proof-of-Concept Study Results in Adults, FDA Supported Initiation of Pediatric Program in Infants. Despite the effectiveness of current vaccines, IPD, which includes meningitis and bacteremia, remains persistent in the first years of life and is a leading cause of invasive disease in children two years of age and under. The burden of disease in the pediatric population underscores the need for a broader-spectrum vaccine.
- 02.18.23 - Apellis' Syfovre Nets First FDA Approval For Geographic Atrophy (geneonline)
  - Apellis Pharmaceuticals has announced the US FDA approval of Syfovre (pegcetacoplan injection) to treat geographic atrophy (GA), an advanced form of age-related macular degeneration (AMD). Syfovre makes history as the first and only FDA-approved treatment for GA, a leading cause of blindness that affects more than one million people in the US and five million people worldwide. The drug's approval for GA covers patients with or without subfoveal involvement and allows for a flexible dosing regimen of every 25 to 60 days.While Syfovre is designed to slow the progression of GA, it does not reverse the atrophy. The approval of the drug is based on positive two-year results from the Phase 3 Oaks and Derby studies, which showed that treatment reduced the rate of GA lesion growth compared to placebo. Increasing treatment effects were observed over time, with the greatest benefit (in Derby, 36% reduction in lesion growth with monthly treatment) occurring between months 18-24.
- 02.28.23 - Sutro Biopharma Appoints Dr. Anne Borgman as Chief Medical Officer (PR)
  - Prior to joining Sutro, Dr. Borgman served as Vice President and Therapeutic Area Lead, Oncology, Hematology, and Transplant, at Jazz Pharmaceuticals, where she was responsible for global drug development for four marketed products and drug development plans for several emerging targets. Previously, Dr. Borgman was Vice President, Clinical Research & Development, at Exelixis, where she was responsible for the global development for cabozantinib and oversaw the development of multiple Phase 3 programs. She has also held leadership positions in Oncology Drug Development at KaloBios Pharmaceuticals, Talon Therapeutics (formerly Hana Biosciences), and Abbott Laboratories. Dr. Borgman currently serves on the Board of Directors at Curis, NextCure, and NiKang Therapeutics and has been a Consulting Associate Professor for the Stanford University School of Medicine and at the University of Chicago.
- 02.22.23 - Gilead Presents Positive Proof-of-Concept Data for Investigational Combination Regimen of Lenacapavir with Broadly Neutralizing Antibodies as a Potential Twice-Yearly Approach for the Treatment of HIV (PR)
  - Study Demonstrates the Potential of Lenacapavir in Combination with Broadly Neutralizing HIV Antibodies Teropavimab and Zinlirvimab. Findings Support Further Evaluation of the Investigational Combination as a Long-Acting HIV Treatment Option in a Phase 2 Study. The combination of lenacapavir with teropavimab and zinlirvimab will advance to a Phase 2 study (NCT05729568) later this year in virologically suppressed people living with HIV. The study will assess two different dose levels of the bNAbs and assess safety and efficacy of the regimen in participants followed longitudinally for multiple doses of the study regimen.
- 02.16.23 - FDA gives green light to Chiesi's Lamzede (pharmaphorum)
  - US regulators have approved Chiesi's Lamzede (velmanase alfa-tycv) as the first enzyme replacement therapy for the treatment of non-central nervous system manifestations of alpha-mannosidosis (AM) in adult and paediatric patients. Lamzede (velmanase alfa-tycv) is a recombinant form of human alpha-mannosidase designed to replace or support the function of the natural enzyme and prevent the build-up of mannose–rich oligosaccharides in various tissues in the body.
- 02.16.23 - Inozyme Pharma Reports Positive Topline Data from Ongoing Phase 1/2 Trials of INZ-701 (PR)
  - Rapid, significant, and sustained increase in plasma pyrophosphate (PPi) observed and encouraging patient reported outcome data in all dose cohorts in ENPP1 Deficiency trial. Rapid and significant increase in PPi observed in all dose cohorts with sustained increase observed in highest dose cohort in ABCC6 Deficiency.(PXE) trial - INZ-701 was generally well-tolerated and exhibited a favorable safety profile in both trials.

- 02.15.23 - Coherus and Junshi Biosciences Announce Positive Final Overall Survival Results of JUPITER-02, a Phase 3 Clinical Trial Evaluating Toripalimab as Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma (PR)
  - The FDA has granted Breakthrough Therapy designations and priority review for the toripalimab Biologics License Application ("BLA") for use in combination with gemcitabine and cisplatin as first-line treatment for patients with advanced recurrent or metastatic NPC and for toripalimab monotherapy for the second-line or later treatment of recurrent or metastatic NPC after platinum-containing chemotherapy. Recurrent or metastatic NPC is an aggressive head and neck tumor which has no FDA-approved treatment options.
- 02.14.23 - Kinnate Biopharma Inc. Receives Fast Track Designation from the U.S. Food and Drug Administration for KIN-3248, an Investigational Pan-FGFR Inhibitor (PR)
  - Fast Track designation for Kinnate's investigational pan-FGFR inhibitor, KIN-3248, for the treatment of patients with unresectable, locally advanced or metastatic cholangiocarcinoma (CCA) harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other alterations, who have received at least one prior systemic therapy. Cholangiocarcinoma, also known as bile duct cancer, is a rare condition, often diagnosed when it is advanced. Research has shown that FGFR is an actionable alteration in patients with CCA. FGFRs are tyrosine kinases that play a crucial role in cell proliferation, differentiation, migration and survival. FGFR2 gene fusions or other alterations are identified in approximately 16% of intrahepatic cholangiocarcinoma (ICC) tumors.
- 02.13.23 - Exelixis and Sairopa Announce US FDA Clears Investigational New Drug Application for ADU-1805 in Patients with Advanced Solid Tumors (PR)
  - Under the terms of the clinical development and option agreement announced in November 2022, Exelixis has the option to obtain an exclusive, worldwide license to develop and commercialize ADU-1805 and other anti-SIRPα antibodies upon review of data from prespecified phase 1 clinical studies of ADU-1805 to be completed by Sairopa during the option period. This IND clearance triggers a $35 million milestone payment to Sairopa which will be paid in the first quarter of 2023.
- 02.13.23 - Opdivo® (nivolumab) in Combination with CABOMETYX® (cabozantinib) Shows Durable Survival with Over Three Years of Follow-Up in the CheckMate -9ER Trial in First-Line Advanced Renal Cell Carcinoma (PR)
  - Data to be featured at ASCO GU 2023 demonstrate continued overall survival, progression-free survival and objective response rate benefits with Opdivo in combination with CABOMETYX compared to sunitinib, regardless of IMDC risk score. These three-year data – with a median follow-up of 44 months – from CheckMate -9ER represent the longest reported follow-up in any Phase 3 trial with an immunotherapy-tyrosine kinase inhibitor regimen in this population. In an exploratory biomarker analysis, median progression-free survival and overall survival were improved with the combination of Opdivo and CABOMETYX regardless of PD-L1 status
- 02.10.23 - Incyte Announces 52-Week Results from Phase 2 Study Evaluating Povorcitinib (INCB54707) in Patients with Hidradenitis Suppurativa (PR)
  - Results from open-label extension period of the Phase 2 trial demonstrate that longer-term treatment with povorcitinib 75 mg resulted in sustained and durable efficacy across all treatment arms. Data featured as an oral presentation at the European Hidradenitis Suppurativa Foundation conference. Hidradenitis suppurativa (HS) is a chronic and debilitating inflammatory skin condition characterized by painful nodules and abscesses that can lead to irreversible tissue destruction and scarring
- 02.10.23 - Mineralys, amid signs of thawing IPO market, upsizes offering to raise $192M for race with AstraZeneca (fiercebiotech)
  - In the first half of 2023, Mineralys plans to start a phase 2 clinical trial to evaluate its lead candidate, the aldosterone synthase inhibitor lorundrostat, as an add-on drug in patients with uncontrolled or resistant hypertension (uHTN/rHTN). It also expects to kick off another phase 2 trial of lorundrostat for the treatment of uHTN and rHTN in a chronic kidney disease population around the midpoint of the year.

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