Latest oncology clinical development updates

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OTW News Highlights this week

- AdvanCell Enters Into Strategic Collaboration with Lilly to Advance Novel Targeted Alpha Therapies for the Treatment of Cancer
- Immuneering's Clinical Supply Agreement with Regeneron Pharmaceuticals to Evaluate IMM-1-104 in Combination with Libtayo® (cemiplimab) Announced
- Gradalis Secures FDA Regenerative Medicine Advanced Therapy (RMAT) Designation for Vigil® (Gemogenovatucel-T) for Advanced Ovarian Cancer
- Auron Therapeutics Announces FDA Clearance to Initiate Clinical Development of AUTX-703 and Completion of Series B Financing
- Ph 3 waveLINE-010 Trial of Zilovertamab Vedotin for the Treatment of 1L DLBCL Patients initiated
- Positive Ziftomenib Monotherapy Registrational Trial and Positive FDA Feedback for Upcoming Frontline Combination Trial Designs Announced

[Serplulimab Approved in the EU for 1L Treatment of ES-SCLC]

Dr. Jason Zhu, Executive Director and Chief Executive Officer of Henlius, stated: “The approval of serplulimab in the EU represents another significant step forward in our mission to benefit patients worldwide. This milestone not only underscores our leadership in innovative drug development and global strategy, but also brings new hope to ES-SCLC patients in Europe and beyond. Moving forward, we ...

Read more Drug Approvals

[All clinical studies evaluating TIDAL-01 to discontinue and further development of the program halted]

“Manufacturing for our Selected TIL therapy requires continued investment in process improvements. Due to these capital-intensive requirements and after careful review of future funding needs and the current financial markets, the Company has decided to discontinue development of TIDAL-01 and to conclude all clinical studies evaluating the program in solid tumors,” said Sammy Farah, M.B.A., Ph.D., Turnstone’s President and Chief ...

[US FDA Grants Orphan Drug Designation to 225Ac-SSO110 (satoreotide) for the treatment of patients with SCLC]

Manfred Rüdiger, Chief Executive Officer at Ariceum Therapeutics, said: “Receiving ODD for 225Ac-satoreotide is a recognition of its potential as a treatment option for patients with SCLC and an important regulatory milestone for Ariceum. The FDA’s ODD will support our objective to accelerate the development of 225Ac-satoreotide through human trials to provide a potentially life-saving therapy to patients with limited ...

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[Positive updated data from THIO-101 pivotal Ph 2 trial of THIO + Libtayo in patients with advanced NSCLC who failed two or more SOC regimens announced]

“Treatment with THIO now shows a 99% probability that overall survival will extend past chemotherapy’s measure by a wide margin,” said Vlad Vitoc, M.D., CEO of MAIA. “THIO’s efficacy in advanced stages of NSCLC continues to exceed our expectations, especially in third-line treatment where the cancer is typically even more resistant to therapy. Our findings suggest great benefits to patients ...

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First Enrolled Subject in the THANK-u Plus™ Platform-Based Allogeneic CAR-T Trial Achieves sCR at Week 4

“Developed in-house, the THANK-u Plus™ platform is an innovative allogeneic CAR-T technology designed to overcome the accessibility challenges in CAR-T therapy. The expansion of CAR-T cells and the preliminary positive efficacy observed in the first subject further reinforce our confidence in the future of allogeneic CAR-T products development. We extend our sincere gratitude to the investigators for their invaluable collaboration ...

Read more Trial Status

Invenra and Orion Announce Discovery Service and Commercial License Agreement to Develop Innovative Bispecific Antibody Cancer Therapeutics

“This collaboration highlights the strength and versatility of our B-Body® platform in addressing complex biological challenges,” said Roland Green, CEO of Invenra. “We are thrilled to work with Orion, a company that shares our commitment to delivering innovative therapies that address critical unmet medical needs.”

AdvanCell Successfully Completes an Oversubscribed US$112M Series C Financing

“This successful Series C round demonstrates strong confidence in our vision and capabilities,” said Andrew Adamovich, CEO of AdvanCell. “We are grateful for the continued support from our existing investors, particularly the long-term support from Morningside and are excited to welcome new partners who share our commitment to transforming cancer care. With this funding, AdvanCell is well-positioned to scale our ...

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