



Latest oncology clinical development updates

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OTW News Highlights this week

- [SC Pembrolizumab With Berahyaluronidase Alfa Demonstrates Noninferior PK Compared to IV KEYTRUDA in Pivotal 3475A-D77 Trial](#)
- [FAILED TRIAL: Ph 3 ARTISTRY-7 Trial of Nemvaleukin + KEYTRUDA in Patients with Platinum-Resistant Ovarian Cancer did not achieve a statistically significant improvement in OS](#)
- [Primary Endpoint Met in Pivotal Ph 3 ROSELLA Trial of Relacorilant in Patients with Platinum-Resistant Ovarian Cancer](#)
- [Ph 3 Study Design Finalized with FDA for IMNN-001 in Newly Diagnosed Advanced Ovarian Cancer](#)
- [TIVDAK \(tisotumab vedotin\) Approved by European Commission for Previously Treated Recurrent or Metastatic Cervical Cancer](#)
- [RYBREVANT \(amivantamab-vmjw\) + LAZCLUZE \(lazertinib\) outperform osimertinib with a significant OS benefit in patients with EGFR-mutated NSCLC](#)
- [Positive CHMP Opinion for the SC Formulation of Opdivo® \(nivolumab\) Across Multiple Solid Tumor Indications](#)

- [FDA approves Pluvicto for earlier use before chemotherapy in PSMA-positive metastatic CRPC](#)



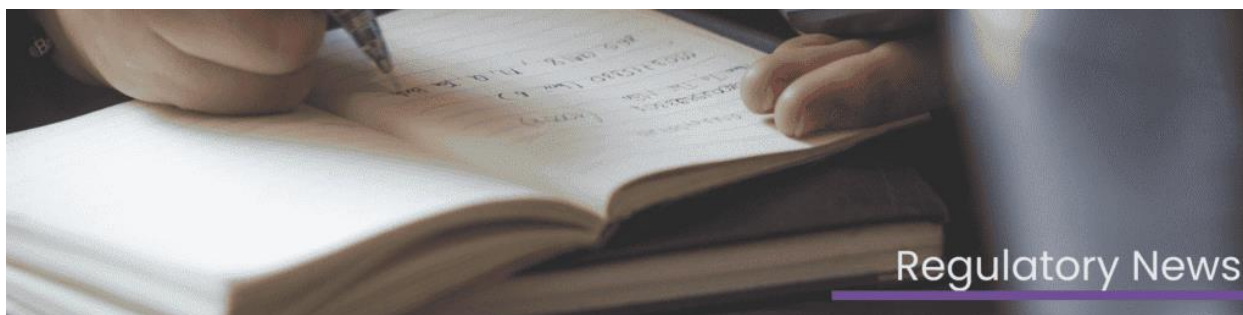
[U.S. FDA Approves CABOMETYX for Patients with Previously Treated Advanced Neuroendocrine Tumors](#)

“As a company committed to improving the standard of care for people living with advanced, difficult-to-treat cancers, we are proud to bring CABOMETYX to patients with previously treated advanced neuroendocrine tumors,” said Amy Peterson, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. “I would like to extend our sincere gratitude to the Alliance for ...

[Imfinzi approved in the US as perioperative immunotherapy for patients with muscle-invasive bladder cancer](#)

Dave Fredrickson, Executive Vice President, Oncology Haematology Business Unit, AstraZeneca, said: “Today’s approval for Imfinzi represents a paradigm shift, bringing the first perioperative immunotherapy to patients in the US with muscle-invasive bladder cancer and addressing a significant need for better treatment options. The NIAGARA trial showed more than 80 percent of patients were still alive at two years, underscoring the ...

[Read more Drug Approvals](#)



[NMPA Breakthrough Therapy Designation for IBI363 in Melanoma](#)

Dr. Hui Zhou, Senior Vice President of Innovent, said, “As Innovent’s first-in-class next-generation IO therapy, IBI363 simultaneously and selectively inhibits the PD-1/PD-L1 pathway and activates the IL-2 pathway. IBI363 has recently received multiple FTD and BTD designations, signifying regulatory recognition of its clinical value in addressing unmet medical needs. Non-cutaneous melanoma subtypes like mucosal melanoma—which are more prevalent in China—are ...

[FDA Clears IND Application for Ph 1 Trial of RB-164 for Hematologic and Solid Malignancies](#)

“Radiance marks the clearance by the FDA of the IND application for RB-164™ to be a significant milestone for the Company, with its first clinical-stage product candidate to advance into clinic for treating unmet needs in major cancer indications,” said Robert Brooks, JD, Chief Executive Officer.

[Read more Regulatory News](#)



[Results Announced from Ph 2a Trial of VXM01 and Avelumab Combination Therapy in GBM](#)

"The completion of this Phase 2a study is a significant milestone for Vaximm AG, as it provides strong evidence that VXM01, in combination with avelumab is generally well-tolerated in patients with recurrent glioblastoma," said Dr. Constance Hoefer, CEO of Vaximm AG. "We are encouraged by these early results and the potential to improve outcomes for patients with this aggressive cancer. ...

[In LAURA Ph 3 trial, Tagrisso continues to demonstrate improved OS trend in unresectable, Stage III setting](#)

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "Having now treated more than one million patients around the world, Tagrisso has repeatedly transformed expectations for patients with EGFR-mutated lung cancer by not only extending survival but also showing it is possible to maintain quality of life during cancer treatment. The breadth of data at ELCC reinforce Tagrisso as ...

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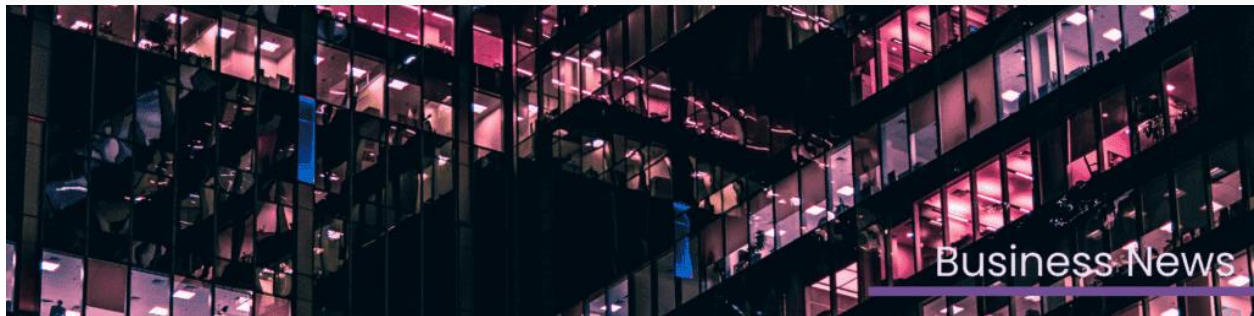


[First Patient Dosed in the Ph 3 Registrational Trial of ICP-248 + Orelabrutinib as First-Line Therapy for Treatment of CLL/SLL Patients in China](#)

Dr. Jasmine Cui, the co-founder, chairwoman and CEO of InnoCare, said, "The treatment of CLL/SLL has achieved significant breakthroughs in recent years, and chemo-free regimens are gradually becoming the preferred approach. ICP-248 plays an important role

in InnoCare's extensive hemato-oncology pipeline. Together, ICP-248, orelabrutinib and tafasitamab form a robust product combination that reinforces InnoCare's leadership in the treatment of hematologic ...

[Read more Trial Status](#)



[Bayer and Puhe BioPharma enter into global license agreement for Ph 1 PRMT5 inhibitor](#)

“We are looking forward to explore the potential of the PRMT5 inhibitor, which could improve outcomes for patients with MTAP-deleted tumors who often have a poor prognosis,” said Juergen Eckhardt, M.D., Head of Business Development and Licensing at Bayer’s Pharmaceuticals Division. “The highly selective targeting of cancer cells while sparing healthy cells, based on the innovative mechanism of action is ...

[Relmada Therapeutics Licenses Ph 2 Bladder Cancer Candidate, NDV-01, from Trigone Pharma](#)

“We are delighted to add NDV-01 to our pipeline as we believe it represents an exceptional value-creation opportunity for Relmada and our investors. The drug development expertise of our Team provides flexibility to be opportunistic and consider programs that have the potential to be high-value assets and that can demonstrate proof-of-concept in the near-term, regardless of therapeutic area. NDV-01 is ...

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