



# MedNess

## Onco-This-Week

*bite-size biopharma and medtech news*

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### MedNess News Highlights this week

Foundation Medicine

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## IDEAYA Announces Clinical Study Collaboration with Gilead Sciences to Evaluate Trodelvy® and IDE397 Combination in MTAP-Deletion Bladder Cancer

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## Exelixis and Arcus Biosciences Announce Clinical Trial Collaboration to Evaluate Zanzalintinib in Combination with AB521 in Patients with Advanced RCC

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## First Patient Enrolled in Phase 2 Clinical Study Evaluating BDC-1001 in Patients with HER2-Positive Breast Cancer Previously Treated with Enhertu

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## STELLAR-305 Phase 2/3 Pivotal Trial of Zanzalintinib + Pembrolizumab in Patients with Previously Untreated Recurrent or Metastatic Head and Neck Cancer announced

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## FDA Grants Priority Review of sBLA for ELAHERE® (mirvetuximab soravtansine-gynx) in Platinum-Resistant Ovarian Cancer

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# MedNess Diagnostics

## Foundation Medicine

Foundation Medicine stands as an early innovator, harnessing genomics technologies for scalable, high-throughput cancer gene mutation profiling-based diagnoses. Established in 2010 in Cambridge, Massachusetts, the company's first product, FoundationOne, was launched in 2012 as a tissue-based test. This was followed by FoundationOne Heme in 2013, an NGS based comprehensive genome...

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# MedNess Neuro

## **Aquinnah's potential Alzheimer's drug capable of reducing ~70% brain tau pathology**

Aquinnah Pharmaceuticals recently announced the preclinical findings on its novel therapeutic designed to slow or stop the progression of Alzheimer's Disease (AD) and related disorders. Their drug discovery relies on identifying compounds capable of eliminating persistent stress granules. Stress granules are aggregates of proteins and RNA molecules formed as a cell...

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## Drug approvals

### **Abecma Becomes First CAR T Approved for Use in Earlier Lines of Therapy for Patients with Relapsed or Refractory Multiple Myeloma in Japan**

Commenting on the approval, Makoto Sugita, Bristol Myers Squibb's head of R&D in Japan, said, "Multiple myeloma is an intractable disease with recurrent relapses that are difficult to cure with existing therapies. Treatment options for patients with RRMM are limited, and we are pleased that Abecma is the first CAR...

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## Regulatory news

## **FDA Grants Priority Review of sBLA for ELAHERE® (mirvetuximab soravtansine-gynx) in Platinum-Resistant Ovarian Cancer**

“With the FDA’s filing of our sBLA, we are one step closer to securing full approval of ELAHERE in the US and establishing this novel ADC as the standard of care in FRα-positive platinum-resistant ovarian cancer,” said Michael Vasconcelles, MD, ImmunoGen’s Executive Vice President, Research, Development, and Medical Affairs. “This...

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## **Both FDA Fast Track and Breakthrough Therapy Designation for Cretostimogene Grenadenorepvec in High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer**

“Receiving both FDA Fast Track and Breakthrough Therapy Designation is an important milestone in the development of cretostimogene grenadenorepvec and for patients with bladder cancer who urgently need more therapeutic options,” said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. “We are encouraged by this momentum following our recent...

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# Trial results

## **KEYLYNK-008 Trial of KEYTRUDA + LYNPARZA for Patients With Metastatic Squamous NSCLC to Stop for Futility**

“While there have been significant scientific advancements in lung cancer research in recent years, unmet needs remain for patients with advanced non-small cell lung cancer,” said Dr. Marjorie Green, senior vice president and head of late-stage oncology, global clinical development, Merck Research Laboratories. “We sincerely thank the patients and investigators...”

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## **FAILED TRIAL: Phase 3 LEAP-001 Trial Evaluating KEYTRUDA + LENVIMA as 1L Treatment for Patients with Advanced or Recurrent Endometrial Carcinoma did not meet primary dual endpoints**

“We remain confident in the proven benefit of KEYTRUDA plus LENVIMA for the treatment of appropriate patients with certain types of previously treated advanced endometrial carcinoma based on results from the KEYNOTE-775/Study 309 trial and will continue to research the KEYTRUDA plus LENVIMA combination in patients with other types of...”

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# Trial status

## **First Patient Enrolled in Phase 2 Clinical Study Evaluating BDC-1001 in Patients with HER2-Positive Breast Cancer Previously Treated with Enhertu**

“The dosing of the first patient in this trial is a significant achievement in our efforts to find new treatment options for patients with HER2-positive breast cancer that continues to progress after treatment,” said Kang, a principal investigator on the study. “Despite the numerous HER2-targeted therapeutics approved for treating advanced...

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## **STELLAR-305 Phase 2/3 Pivotal Trial of Zanzalintinib + Pembrolizumab in Patients with Previously Untreated Recurrent or Metastatic Head and Neck Cancer announced**

“We are excited to progress zanzalintinib, our next-generation multi-targeted tyrosine kinase inhibitor, into this population of patients who otherwise are relegated to immunotherapy plus chemotherapy, but may benefit from a chemo-free option,” said Amy Peterson, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. “This...

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# Conference Coverage

## **CONFERENCE COVERAGE: 2023 SITC Annual Meeting**

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## Business News

### **IDEAYA Announces Clinical Study Collaboration with Gilead Sciences to Evaluate Trodelvy® and IDE397 Combination in MTAP-Deletion Bladder Cancer**

“We are delighted to enter into this clinical collaboration with Gilead that advances our multi-pronged strategy designed to deliver maximal benefit to MTAP-deletion solid tumor patients. We believe the strong mechanistic rationale of this combination, and the monotherapy efficacy observed by both agents in MTAP-deletion bladder cancer, may enable this...

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## **Exelixis and Arcus Biosciences Announce Clinical Trial Collaboration to Evaluate Zanzalintinib in Combination with AB521 in Patients with Advanced RCC**

“We are excited to learn more about the potential effects of zanzalintinib plus Arcus’ HIF-2 $\alpha$  inhibitor, as these two molecules approach the inhibition of cancer cell proliferation and tumor angiogenesis from differing angles, and combination therapy may provide better outcomes than either therapy alone,” said Amy Peterson, M.D., Executive Vice...

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