



# MedNess

*bite-size biopharma and medtech news*

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## MedNess News Highlights this week

FDA Approves KEYTRUDA® (pembrolizumab) Plus Chemoradiotherapy as Treatment for Patients With FIGO 2014 Stage III-IVA Cervical Cancer

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TIVDAK® sBLA Accepted for Priority Review by FDA for Patients with Recurrent or Metastatic Cervical Cancer

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## Clinical Response Update on AFM24-102 Trial in EGFR-wildtype Non-Small Cell Lung Cancer Provided

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## Last Patient Enrolled in Phase 3 TRIDENT Trial in Newly Diagnosed Glioblastoma

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## Boehringer Ingelheim and 3T Biosciences signed a second T-cell focused collaboration

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## Onco-This-Week

### Drug Approvals

#### **European Commission Approves KRAZATI (adagrasib) for Patients with Advanced NSCLC with a KRASG12C Mutation**

“KRAZATI offers an efficacious and tolerable therapeutic option for patients living with advanced KRASG12C -mutated NSCLC and this approval expands the potential treatment options available,” Martin Reck, MD, PhD, Lung Clinic Grosshansdorf, Germany. “With its differentiated profile, KRAZATI offers an impactful treatment option for patients living with lung cancer. This...

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## **FDA Approves KEYTRUDA® (pembrolizumab) Plus Chemoradiotherapy as Treatment for Patients With FIGO 2014 Stage III-IVA Cervical Cancer**

“Today’s approval of KEYTRUDA plus chemoradiotherapy is welcome news and gives patients with newly diagnosed FIGO 2014 Stage III-IVA cervical cancer, for the first time ever, the option of an anti-PD-1-based regimen to treat their cancer,” said Dr. Bradley Monk, oncologist and professor of obstetrics and gynecology at University of...

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## Regulatory News

### **TIVDAK® sBLA Accepted for Priority Review by FDA for Patients with Recurrent or Metastatic Cervical Cancer**

“The Phase 3 innovaTV 301 trial demonstrated a favorable benefit/risk profile, including improvement in overall survival, and adds to the overall data supporting TIVDAK as a treatment option for people with recurrent and metastatic cervical cancer who have limited treatment options,” said Roger Dansey, M.D., Chief Development Officer, Oncology at...

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## **Update on Zolbetuximab Biologics License Application in U.S.: FDA rejects the application**

Moitreyee Chatterjee-Kishore, Ph.D., M.B.A., Senior Vice President and Head of Immuno-Oncology Development, Astellas said, “We remain confident in zolbetuximab’s clinical profile and potential to fill a significant therapeutic gap for those diagnosed with advanced gastric or GEJ cancer whose tumors are CLDN18.2 positive. Astellas is committed to working with the...

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## **Trial Results**

### **Clinical Response Update on AFM24-102 Trial in EGFR-wildtype Non-Small Cell Lung Cancer Provided**

“We are encouraged by the responses in these patients who had all progressed on PD1 targeting therapy and made the strategic decision to expand this patient cohort,” said Dr. Andreas Harstrick, CMO and interim Chief Executive Officer of Affimed. “There is a significant unmet need for these patients who have...

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Results**

# Trial Status

## **Last Patient Enrolled in Phase 3 TRIDENT Trial in Newly Diagnosed Glioblastoma**

“TTFields therapy has played a critical role in the treatment of newly diagnosed glioblastoma for nearly a decade, and the TRIDENT trial represents the potential evolution of this treatment paradigm by introducing TTFields earlier, at the same time as radiation therapy and temozolomide,” said Asaf Danziger, Novocure’s Chief Executive Officer....

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## **Enrollment opens for Phase 1b/2 Study Evaluating Ampligen® (rintatolimod) in Combination with Imfinzi® (durvalumab) for the Treatment of Pancreatic Cancer**

Prof. Casper H.J. van Eijck, MD, PhD, the DURIPANC Study’s Coordinating Investigator and a pancreato-biliary surgeon at Erasmus MC, stated, “While immune checkpoint inhibitors targeting PD1/PDL1 have shown promise in other solid tumors, they have shown limited efficacy thus far in ductal cancer of the pancreas. Findings from our previous...

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## Business News

## **Boehringer Ingelheim and 3T Biosciences signed a second T-cell focused collaboration**

“At Boehringer Ingelheim, we are committed to transforming patients’ lives. The initial success of our work with 3T gives us confidence that together we can and will expand and accelerate our pipeline of first-in-class T-cell based anti-cancer therapies,” said Lamine Mbow, Ph.D., Global Head of Cancer Immunology and Immune Modulation,...

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## **AbbVie and Umoja Biopharma Announce Strategic Collaboration to Develop Novel In-Situ CAR-T Cell Therapies**

“As we continue to strengthen our oncology portfolio, we believe that in-situ CAR-T cell therapy represents a paradigm shift utilizing genetic medicine concepts,” said Jonathon Sedgwick, Ph.D., vice president and global head of discovery research at AbbVie. “We look forward to working with Umoja’s team to advance next-generation in-situ CAR-T...

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