



Flamingo Therapeutics and Dynacure Announce Merger to Create Leading RNA Therapeutics Company Focused on Clinical Oncology

-Combined company to be named Flamingo Therapeutics, focused on advancing Flamingo's asset danvatirsen in a Phase II trial PEMDA-HN in Head & Neck cancer and IND-ready program targeting MALAT-1 (FTX-001), in oncology-

-Merger leverages common synergies of Flamingo and Dynacure, including deep expertise in RNA-targeting and clinical drug development-

Leuven (Belgium), Strasbourg (France), Philadelphia (USA)- March 2, 2023 /PRNewswire/-- Flamingo Therapeutics ("Flamingo") and Dynacure, announced today that the companies have signed a definitive merger agreement to combine their pipelines and expertise to create a leading oncology company. The combined company will advance Flamingo's lead programs: danvatirsen in a Phase II trial PEMDA-HN in Head & Neck cancer (danvatirsen in combination with pembrolizumab) and other indications; and FTX-001 targeting MALAT-1 in cancer (IND ready). In addition, Flamingo's current investors Kurma Partners (France) and PMV (Belgium) made a further investment in the company.

Danvatirsen is an antisense oligonucleotide (ASO) that selectively targets STAT3 and has shown clinical activity in two Phase II clinical studies. Danvatirsen binds to STAT3 mRNA, inhibiting translation of the transcript. The therapeutic effect of STAT3 suppression results in reduction of tumor cell growth as well as activation of anti-tumor immunity mediated by the tumor micro-environment.

Currently, danvatirsen is planned to continue Phase 2 clinical development for head and neck squamous cell carcinoma to advance the program through key clinical milestones and data readouts. In addition, the combined company will also advance FTX-001, Flamingo's most advanced long non-coding RNA (LncRNA) program which targets MALAT-1, through readiness for Phase 1 in solid tumors. LncRNAs are a large and untapped class of disease-causing targets within the "dark matter" of the human genome.

"The merger of Flamingo and Dynacure is a great strategic fit for both companies, leveraging a wealth of RNA therapeutic expertise and cancer drug development, and combining teams to create a stronger organization," said Stephane van Rooijen, Chief Executive Officer of Flamingo. "With our well-defined clinical strategy and operational plan, we are focused on creating value for all stakeholders, including patients, clinicians, and our investors. We plan to continue to execute upon our clinical strategy with the combined company and team in place."

“We are delighted to join forces with the Dynacure team to execute an exciting transition plan for the long-term success and growth of Flamingo. The merger will focus our priorities on clinical execution, while adding additional resources,” added Michael Garrett, Chief Operating Officer of Flamingo.

Chris Mirabelli, Ph.D., Chairman of the combined company, added, “We have tremendous confidence in danvatirsen and our MALAT-1 targeted ASO (FTX-001), and look forward to delivering on our ambitious clinical plan with multiple readouts planned for 2024 and 2025.”

Brett P. Monia, Ph.D., Ionis’ Chief Executive Officer, added, “We are pleased that the combined company will advance Ionis-discovered cancer therapies where there is an unmet need, enabling Ionis to focus our resources on our pipeline priorities. The strength and dedication of the Flamingo leadership team, combined with their core expertise in oncology drug development, provide for a compelling foundation for future success for all stakeholders, including Ionis.”

Management and Organization

The combined company will be led by Dynacure’ Chief Executive Officer, Stéphane van Rooijen (MD, MBA) – who will become the combined company’s Chief Executive Officer - and Flamingo’s Chief Executive Officer, Mike Garrett – who will become the combined company’s Chief Operating Officer. The company will be headquartered at the location of its laboratory facilities in Leuven (Belgium) and have offices in Strasbourg (France), and Philadelphia (USA). The combined company’s board of directors will be comprised of members from both Flamingo and Dynacure, including Chris Mirabelli, Ph.D., Chairman of Leap Therapeutics (Nasdaq: LPTX), who will act as Chairman of the combined company, Brett P. Monia, Ph.D., President and Chief Executive Officer of Ionis Pharmaceuticals (Nasdaq: IONS), Benoit Barteau, Tine Bekaert, Rémi Droller, Jean Franchi, George Gemayel, and Henry Skinner.

About PEMDA-HN Phase II trial in Head & Neck cancer

Flamingo Therapeutics is planning to initiate a Phase II trial evaluating the STAT3 targeting agent danvatirsen, in combination with pembrolizumab, in patients with head and neck squamous cell carcinoma (HNSCC).

The trial is planned to be a multicenter, open-label, randomized study comparing the combination of danvatirsen and pembrolizumab to pembrolizumab alone as first line therapy in patients with recurrent/metastatic HNSCC whose tumor has a PD-L1 expression. Eligible patients will be randomized in a 2:1 ratio to receive either danvatirsen + pembrolizumab or pembrolizumab monotherapy, respectively. After the screening period, eligible patients are planned to receive study treatment until disease progression or discontinuation. The planned primary endpoint of the study is to determine the overall response rate by RECIST 1.1 as assessed by the investigator. The secondary endpoints will include safety, duration of response, disease control rate, progression free survival and overall survival. The study is planned to be operated at US study centers.

About Flamingo Therapeutics

Flamingo is pioneering RNA-targeted therapies for oncology with state-of-the-art chemistries and a clinical-stage pipeline targeting undruggable transcription factors and splice variants. Flamingo has an alliance with Ionis Pharmaceuticals and is supported by well-known biotechnology investors including Andera Partners, Bpifrance Large Venture, Bpifrance through its FABS and Fonds Biothérapies Innovantes et Maladies Rares funds, Eurazeo - Kurma Partners, Perceptive Advisors, PMV, Pontifax, Sphera, funds managed by Tekla Capital Management LLC and VIB.

For more information on Flamingo, please visit <https://flamingotx.com> and engage with us on LinkedIn <https://www.linkedin.com/company/flamingo-therapeutics>.

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