OSE Immunotherapeutics Presents Positive Step-1 Phase 3 Results for Tedopi® in NSCLC at the European Society for Medical Oncology Virtual Congress 2020

Data include significant increase to overall survival and good safety profile in non-small cell lung cancer patients after failure with checkpoint inhibitor therapies

Nantes, France, September 21, 2020, 7:30AM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) presented positive results from Step-1 of its Phase 3 trial of neoepitope-based cancer vaccine Tedopi®, in patients with advanced non-small cell lung cancer (NSCLC) after failure of previous checkpoint inhibitor treatments, at the 2020 European Society for Medical Oncology (ESMO) Virtual Conference.

Alexis Peyroles, Chief Executive Officer of OSE Immunotherapeutics, said: *"These are very exciting results for Tedopi® and the improvement in overall survival, which was substantially above the standard of care, demonstrates that our neoepitope cancer vaccine has the potential to make a truly important difference to the lives of advanced NSCLC patients. In addition, the significantly longer survival after progression, the sustained good ECOG performance status* and the strong safety profile for Tedopi® are further reinforcements of its therapeutic value. These results were achieved in a hard to treat cancer patient population after failure of checkpoint inhibitor treatments, further highlighting the robust potential for Tedopi®. We warmly thank all patients, their families, the investigators and the teams who participated in this study."*

- The primary endpoint, 1-year overall survival (OS) rate in the mITT** population, was achieved: a 46% 1-year overall survival (OS) rate for Tedopi® treated patients [95% CI: 33%, 59%] and more than the planned upper limit in the protocol (pre-specified futility boundary H0 <25% to reject; pre-specified alternative efficacy H1> 40% considered as clinically meaningful). This 46% OS rate was 10% higher than the standard of care (SoC) chemotherapy at 36% [95% CI: 21%, 54%].
- 1-year OS rate was confirmed at 47.5% in the modified per protocol*** population (those without major deviations) considered as the targeted population in this indication [95% CI: 34.3%, 60.9%] versus SoC at 34.4% [95% CI: 18.6% 53.2%].
- Median overall survival was longer in the ITT population at 9.8 months in the Tedopi® group versus 8.7 months in the SoC group, HR: 0.71 [95% CI: 0.44, 1.16]; p=0.17.
- Median overall survival difference was statistically significant in the targeted per protocol population with Tedopi® at 11.1 months versus 8.7 months for SoC, p=0.037; HR: 0.57 [95% CI: 0.34, 0.97].
- Other main secondary endpoints included similar disease control rate at 6 and 12 months between the two treatment groups.

- The time to ECOG deterioration was significantly longer in the Tedopi® group (8.4 vs 4.4 months; p=0.002). Survival after progression was also significantly longer in the Tedopi® group (7.5 vs 4.4 months; p=0.022).
- Good tolerance profile of Tedopi® with significantly less severe Treatment Emergent Adverse Effects (TEAS) (Tedopi® 14% vs SoC 43%, p<0.001).

Overall, benefit/risk ratio is favorable for Tedopi® and better than that of SoC in this post checkpoint inhibitors treated population.

Dr. Giuseppe Giaccone, M.D., Chief of thoracic oncology at Weill Cornell Medical College (New York), an internationally recognized expert in the field of lung cancer and developmental therapeutics and Atalante US Principal Investigator, presented these data in a mini-oral presentation at ESMO 2020 (presentation #1260MO). The Step-1 of Atalante data included the first 103 patients enrolled in the Phase 3 trial that completed a 12-month follow up by the data cut-off of February 26, 2020, before COVID-19 impact.

The study was conducted in HLA-A2 positive advanced NSCLC patients entering second- or third- line treatment after progression on immune checkpoint inhibitors (ICI), a patient population with very poor prognosis and currently no alternative treatment options.

** The ECOG score is a performance scale used to quantify the general health condition of a patient. It is subdivided into 5 grades from 0 to 5, ranging from fully active (0) to fully disabled, then to death (5).*

***mITT (multiple Intention-To-Treat) population: all randomized evaluable (≥12 months survival data) patients who received at least one dose of study treatment.*

****Per protocol population: ITT population without protocol major deviations defined after a blind review by NSCLC experts.*

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is a clinical-stage biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company has several scientific and technological platforms including neoepitopes and agonist or antagonist monoclonal antibodies, all ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical and preclinical portfolio has a diversified risk profile:

- **Tedopi®** (innovative combination of neoepitopes): the company's most advanced product; **positive results for Step-1 of the Phase 3 trial** (Atalante 1) in **Non-Small Cell Lung Cancer** post checkpoint inhibitor failure. In **Phase 2 in pancreatic cancer** (TEDOPaM, sponsor GERCOR) in monotherapy and in combination with checkpoint inhibitor Opdivo®.
- **BI 765063** (OSE-172, anti-SIRPα monoclonal antibody): developed in **partnership with Boehringer Ingelheim**; myeloid checkpoint inhibitor in **Phase 1 in advanced solid tumors**.
- **FR104** (anti-CD28 monoclonal antibody): **positive Phase 1 results**; **Phase 2-ready asset in autoimmune diseases or in transplantation**.
- **OSE-127** (humanized monoclonal antibody targeting IL-7 receptor): developed in **partnership with Servier**; **positive Phase 1 results**; two independent **Phase 2** planned in **ulcerative colitis** (OSE sponsor) and in **Sjögren's syndrome** (Servier sponsor) to start in Q4 2020.
- **BiCKI®**: **bispecific fusion protein** platform built on the key backbone component anti-PD-1 (OSE-279) combined with new immunotherapy targets; 2nd generation of PD-(L)1 inhibitors to increase **antitumor efficacity**.

- **CoVepiT**: a **prophylactic vaccine** against **COVID-19**, developed using SARS-CoV-2 optimized neo-epitopes. **Positive preclinical and human ex vivo results in August 2020**, **clinical trial expected to start end of 2020/early 2021**.
  Due to the COVID-19 crisis, accrual of new patients in the clinical trial TEDOPaM is temporarily suspended and initiation timelines for both Phase 2 trials of OSE-127 could be impacted during the coming months.

For more information: **https://ose-immuno.com/en/**
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Contacts

OSE Immunotherapeutics
Sylvie Détry
Sylvie.detry@ose-immuno.com
+33 153 198 757

French Media: FP2COM
Florence Portejoie
fportejoie@fp2com.fr
+33 607 768 283

U.S. Media: LifeSci Communications
Darren Opland, Ph.D.
darren@lifescicomms.com
+1 646 627 8387

U.S. and European Investors
Chris Maggos
chris@lifesciadvisors.com
+41 79 367 6254

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