OSE Immunotherapeutics Presents OSE-230 as a Novel Agonist Monoclonal Antibody Therapy Triggering Resolution of Chronic Inflammation

The first presentation of new data characterizing the anti-ChemR23 antibody was at the FOCIS Virtual Annual Meeting held October 28-31, 2020

Nantes, France, October 30, 2020, 7:30AM CET – OSE Immunotherapeutics (ISIN: FR0012127173; Mnemo: OSE) presented preclinical efficacy data for novel agonist monoclonal antibody therapy, OSE-230, at the 2020 Federation of Clinical Immunology Societies (FOCIS) Annual Meeting being held virtually on October 28-31, 2020. OSE-230 is an agonist antibody against ChemR23, also known as chemerin chemokine-like receptor 1 (CMKLR1), a G-protein coupled receptor (GPCR) expressed on myeloid immune cells known to modulate inflammation.

Persistent inflammation is a characteristic feature of all chronic inflammatory or autoimmune diseases and if not controlled or resolved, it can lead to further tissue damage and give rise to tissue fibrosis with eventual loss of organ function. Most anti-inflammatory agents act using a mechanism that blocks pro-inflammation pathways. In contrast, OSE Immunotherapeutics is developing OSE-230 as a first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to complete the inflammation program and restore tissue integrity.

Nicolas Poirier, Chief Scientific Officer of OSE Immunotherapeutics, said: *"OSE-230 represents a disruptive concept in the resolution of inflammation, a failed process in potentially all chronic inflammatory diseases. The data presented show that OSE-230 is the first monoclonal antibody triggering the activation of specialized receptors of resolution to restore tissue homeostasis, integrity and functions. Chronic inflammatory diseases are the most significant cause of death worldwide* and their incidence is growing, highlighting the patients' need for disruptive innovations to manage such complex diseases. Our findings provide strong evidence for the therapeutic potential of OSE-230 to be developed in various chronic inflammation and autoimmune pathologies and reinforce OSE's position in the immunotherapy field targeting myeloid cells in autoimmune and chronic inflammatory diseases and in immuno-oncology."*

The oral presentation entitled *"Agonist anti-ChemR23 mAb blunts tissue neutrophil accumulation and triggers chronic colitis inflammation resolution"* shows efficacy results for OSE-230 in chronic inflammatory preclinical models and *ex vivo* human models. The main results from the presentation are as follows:

- OSE-230 induces inflammation resolution acceleration *in vivo* in acute inflammatory preclinical models by triggering pro-resolutive programs in macrophages and neutrophils at the site of inflammation.
- More importantly, OSE-230 triggers efficient resolution of inflammation in chronic colitis models which spontaneously do not resolve, with a significant decrease in leukocyte infiltrates, tissue lesions, fibrosis and inflammation-driven tumors.

- Preclinical studies also demonstrated resolution of inflammation in type 1 diabetes and multiple sclerosis models.

These results were based on OSE's key findings:

- Natural resolution of inflammation is elicited by pro-resolving lipids which activate GPCRs to induce neutrophil apoptosis, reduce neutrophil tissue recruitment and promote macrophage efferocytosis.
- Using transcriptional analyses of up to 300 chronic colitis patients, OSE's R&D team identified ChemR23 as a GPCR receptor of the resolution program overexpressed in the inflamed tissues of patients unresponsive to anti-TNFα or anti-α4β7 therapies. In these patients, treatment resistance was strongly associated with bowel mucosal neutrophil accumulation.
- The ChemR23 receptor is mainly expressed by resident tissue macrophages and neutrophils only under inflammatory (TNF, IL-6, LPS) conditions.

*Chronic Inflammation; Roma Pahwa , Amandeep Goyal, Pankaj Bansal, Ishwarlal Jialal; In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan.; 2020 Aug 10.

ABOUT OSE Immunotherapeutics

OSE Immunotherapeutics is an integrated biotechnology company focused on developing and partnering therapies to control the immune system for immuno-oncology and autoimmune diseases. The company's immunology research and development platform is focused on three areas: T-cell-based vaccination, Immuno-Oncology (focus on myeloid targets), Auto-immunity & Inflammation. Its balanced first-in-class clinical and preclinical portfolio has a diversified risk profile:

Vaccine platform

- **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®.
- **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.

Immuno-oncology platform

- **BI 765063** (OSE-172, anti-SIRPα mAb): developed in partnership with Boehringer Ingelheim; myeloid checkpoint inhibitor in Phase 1 in advanced solid tumors.
- **CLEC-1** (novel myeloid checkpoint target): identification of mAb antagonists of CLEC-1 blocking the "Don't Eat Me" signal that increase both tumor cell phagocytosis by macrophages and antigen capture by dendritic cells.
- **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.

Auto-immunity and inflammation platform

- **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.
- **OSE-230** (ChemR23 agonist mAb): first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.
  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:
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