

## Press Release

# ISA Pharmaceuticals Strengthens Strategic Immuno-Oncology Collaboration with Regeneron

**Leiden, The Netherlands, June 17, 2020**, -- ISA Pharmaceuticals B.V., a private clinical-stage immunotherapy company, today announced plans to initiate a potentially pivotal clinical trial for the combination of ISA101b and Libtayo® (cemiplimab) in oropharyngeal cancer, a type of head-and-neck cancer, under its strategic immuno-oncology collaboration with Regeneron. In addition, Regeneron will increase its equity stake in ISA Pharmaceuticals.

The new oropharyngeal cancer trial is the third trial planned under the clinical collaboration between ISA Pharmaceuticals and Regeneron. ISA101b, an immunotherapy targeting human papillomavirus type 16 (HPV16), is currently in a Phase 2 clinical trial for first- and second-line HPV16-positive head-and-neck cancer in combination with Libtayo, a PD-1 inhibitor that is being jointly developed by Regeneron and Sanofi. A second Phase 2 trial investigating the same combination in cervical cancer is also planned. More than 60 percent of head-and-neck cancers and approximately 55 percent of cervical cancers are HPV16 induced.

Under the revised agreement, the clinical collaboration offers a potential shortened path to first approval in the HPV16-positive oncology indications being studied in the next few years. The agreement also streamlines ISA Pharmaceuticals' access to license fees, milestone payments and royalties. Together with the recently secured 20 million Euro loan from the European Investment Bank, development of ISA101b is now fully funded through the data readout of ongoing and planned pivotal trials which will support regulatory filings.

"This agreement will accelerate the development and commercialization of our lead asset, ISA101b, to treat two important cancers with high unmet medical needs," commented **Gerben Moolhuizen, Chief Executive Officer of ISA Pharmaceuticals**. "We are extremely pleased to be working with Regeneron and for their continued support of both ISA Pharmaceuticals and our clinical studies in both indications."

"Thanks to this updated clinical collaboration, we are able to rapidly diversify our research into a broader array of HPV16-induced cancers," said **Israel Lowy, M.D., Ph.D., Senior Vice President, Translational and Clinical Sciences, Oncology, at Regeneron**. "ISA101b offers a validated mechanism of action, and we look forward to working with ISA Pharmaceuticals to determine the synergistic potential of combining this novel immunotherapy with Libtayo to better address these difficult-to-treat cancers."

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### **About ISA 101b**

ISA101b is a Synthetic Long Peptide (SLP®) therapeutic designed to mount a highly specific T-cell mediated attack by the immune system on tumors positive for human papilloma virus type 16 (HPV16). The product has successfully and safely completed multiple human clinical studies in over 200 patients

- ISA101 has been shown to be effective in patients with early stage, HPV 16 positive, premalignant cancers<sup>1</sup>.
- In late stage, HPV16 positive cervical cancer ISA101b has been shown to act complementary to chemotherapy in terms of clinical benefits.<sup>2,3</sup> Late-stage cancer patients suffer from local and systemic immunosuppression by immune suppressive myeloid cells. Standard of care chemotherapy regimens such as carboplatin and paclitaxel deplete these immune suppressive cells, whilst also having a direct anti-tumour effect and further enable ISA101b to effectively attack the cancer via a T-cell mediated immune response.
- Importantly in a Phase 2, open label, Proof of Concept study, ISA101b in combination with nivolumab (anti-PD1 antibody) has shown tumour response rates and overall survival approx. double to those seen with anti-PD1 monotherapy in 2<sup>nd</sup> line head and neck cancer positive for HPV16<sup>4</sup>.

ISA is currently carrying out a randomized, controlled phase 2 trial of ISA101b in combination with Libtayo in head and neck cancer, under the agreement with Regeneron. Further clinical trials are under preparation.

### **About ISA Pharmaceuticals**

ISA Pharmaceuticals is an immunotherapy company developing treatments for various cancers and infectious diseases. ISA Pharmaceuticals has best-in-class technology to stimulate and activate the human immune system, specifically T cells, to fight diseased or infected cells. ISA Pharmaceuticals has a collaboration with Regeneron for its lead asset, ISA101b, an immunotherapy targeting human papillomavirus type 16 (HPV16)-induced cancer. ISA101b is currently in a Phase 2 clinical trial for first- and second-line HPV16-induced head-and-neck cancer, in combination with Libtayo, a PD-1 antibody. For more information, please visit [www.isa-pharma.com](http://www.isa-pharma.com).

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