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Oncodesign announces the selection of its First-in-Class RIPK2 inhibitor drug candidate for auto-immune and inflammatory diseases

- Demonstration of efficacy in a model of ulcerative colitis¹ and intestinal disorders induced by immunotherapies
- IND expected in 2021
- Drug candidate has blockbuster potential in view of disease indications that could be addressed
- Oncodesign to initiate partnering discussions from early 2020

Dijon, December 17, 2019 à 06:00pm CEST – ONCODESIGN (ALONC – FR0011766229), a biopharmaceutical group specialized in precision medicine, today announced the selection of ODS-101 as a drug candidate for auto-immune and inflammatory disease indications.

Dr. Jan Hoflack, CSO at Oncodesign, explained: "We are excited by the profile and the pharmacology results of ODS-101. The compound satisfies all stringent criteria that we set forward for its use in chronic auto-immune and inflammatory conditions."

Discovered and selected through Oncodesign's proprietary technology platform, ODS-101 is a highly potent and selective inhibitor of the kinase RIPK2 (Receptor Interacting Protein Kinase 2), an essential enzyme of the innate immune system. RIPK2 is a key component in the activation of the NOD (Nucleotide-binding Oligomerization Domain proteins) signaling pathway that plays a pivotal role in the defense mechanism against bacterial infections. In humans, deregulated NOD signaling has been linked to multiple auto-immune and inflammatory conditions, including Crohn's disease, Ulcerative Colitis, Blau syndrome and early onset sarcoidosis. Additional potential indications for inhibitory compounds of a deregulated RIPK2/NOD system include rheumatoid arthritis and multiple sclerosis, amongst others. The discovery of ODS-101 will allow Oncodesign to explore these different potential indications in deeper detail.

In June this year, Oncodesign announced the advancement of its RIPK2 inhibitor program to the pre-candidate stage. Over the past 6 months, ODS-101 has successfully passed all criteria required for its Candidate Drug nomination, including an evaluation in preclinical pharmacology models and a 2 weeks oral toxicology study in rats. ODS-101 is well tolerated and demonstrates promising dose-dependent efficacy results in different colitis models. Other studies are still ongoing or planned.

Today, Oncodesign has selected ODS-101 as a First-in-Class oral RIPK2 inhibitor to advance in IND enabling studies rapidly to reach an anticipated IND status in 2021.

Auto-immune and inflammatory diseases (AIID) encompass more than 150 diseases, hitting 5 to 7% of the population in western countries. They represent the largest pharmaceutical market by revenue. The AIID market was valued at \$143 billion in 2018². However, in many indications the current treatments lead to partial responses and there is a substantial need for additional differentiating therapies. Most of current treatments belong to the antibodies class, which are administered through the intravenous route. Next-generation approaches such as small molecule kinase inhibitors, administered orally, have the potential to add significant therapeutic value in this domain.

 $^{^{}m 1}$ Chronic digestive disease characterized by inflammation of the inner lining of the colon

² D&Consultants, 2019



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"This exceptional result is the product of the choices and investments we have made over the past 36 months to build our portfolio of promising drug candidates. This RIPK2 kinase inhibitor is the first drug candidate to be generated in our laboratories since their creation 25 years ago to the day. This discovery, which demonstrates the ability of our Nanocyclix technology to generate powerful and new drug candidates, also validates the relevance of our strategy deployed in 2010. It is also a sign of the high competence of our teams in the field of Drug Discovery, that I would like to congratulate them greatly on this remarkable performance. With the signing of our service partnerships with Galderma and the search for drug candidates on the LRRK2 target with Servier, we have just aligned our third planet within the indicated time frame. The potential pathologies addressed by our patent RIPK2 inhibitor make it a potential blockbuster that can change the nature and perception of Oncodesign. Our sustained efforts are aimed at providing therapeutic solutions quickly to patients who do not currently have one. This success is also an opportunity for us to thank all our shareholders and partners for their daily support, thank them for their trust, and hope that the coming months will prove them right," said Philippe Genne, PhD, Chairman and CEO and founder of Oncodesign.

Dr. Jan Hoflack, CSO at Oncodesign, added: "As a First-in-Class agent, there is still a lot to be discovered about additional indications for our RIPK2 inhibitor. Extensive studies are ongoing to understand the full scope of this innovative approach: ODS-101 has the potential to be a therapeutic breakthrough addressing many disease indications with remaining unmet need for patients. The identification of our first RIPK2 drug candidate is the result of extensive research in our labs since 2010, and I would like to thank all contributors to this program. We are all looking forward to the advancement of ODS-101 towards IND declaration in 2021 for a potential first administration in men the same year. In addition to the ongoing studies, we will now intensify the search for a first-rate partner to help us develop the full potential of our drug candidate. In particular, our program will be presented to several leading companies in the field of autoimmune and inflammatory diseases at the 38th JP Morgan Healthcare Annual Congress, to be held from January 13-16, 2020 in San Francisco, California, USA."

About ONCODESIGN: www.oncodesign.com

Founded 25 years ago by Dr. Philippe Genne, the Company's CEO and Chairman, Oncodesign is a biopharmaceutical company dedicated to precision medicine. With its unique experience acquired by working with more than 600 clients, including the world's largest pharmaceutical companies, along with its comprehensive technological platform combining state-of-the-art medicinal chemistry, pharmacology, regulated bioanalysis, medical imaging and Artificial Intelligence, Oncodesign is able to predict and identify, at a very early stage, each molecule's therapeutic usefulness and potential to become an effective drug. Applied to kinase inhibitors, which represent a market estimated at over \$46 billion in 2016 and accounting for almost 25% of the pharmaceutical industry's R&D expenditure, Oncodesign's technology has already enabled the targeting of several promising molecules with substantial therapeutic potential, in oncology and elsewhere, along with partnerships with pharmaceutical groups such as Bristol-Myers Squibb. Oncodesign is based in Dijon, France, in the heart of the town's university and hospital hub, and within the Paris-Saclay cluster. Oncodesign has 232 employees and subsidiaries in Canada and the USA.

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