

Noviga Research AB

NOV202

A Novel Small Molecule Compound Series For
The Treatment of Refractory Cancer

A Business Opportunity in Cancer Therapy

Non-Confidential Information

2016

Company Background

Noviga Research AB (www.novigaresearch.com) is a newly founded Swedish Pharma/Biotech Company focused on the development of novel small molecule drugs for the treatment of diseases with high unmet medical need, such as cancer. The company is based at the Biovation Park (former AstraZeneca R&D facility) in Södertälje, Sweden. Noviga recently acquired the intellectual property rights to a focused small molecule anti-cancer library, including all the data generated around these compounds. Several lead compounds from the library have been shown to have potent *in vitro* and *in vivo* anti-proliferative properties, including both solid and hematological malignancies. The most advanced compound, *NOV202*, is close to entering GLP-tox studies.

Target Indication Opportunity: Refractory Cancer Treatment

Overall, approximately 70% of patients diagnosed with ovarian epithelial cancer will relapse after first-line platinum- and taxane-based chemotherapy, and thus there is a large unmet need for novel and safe second line therapies.

Furthermore, a significant proportion of breast and lung cancer patients, comprising around 20% of all cancer patients, also develop resistance to taxane-based chemotherapy, underlining the critical need for new therapeutic approaches.

Preclinical studies have shown that Noviga's lead compound, *NOV202*, could be of clinical benefit to these specific patient populations, which warrant the clinical development of this compound.

Noviga's Drug Product – *NOV202*: Unique Properties

The anti-cancer drug candidate *NOV202* is a small-molecule microtubule-targeting agent for both intravenous and oral administration. *NOV202* was identified from Noviga's compound library as one of the most potent anti-proliferative compound in a large panel of cancer cell lines, including both solid and hematological malignancies.

It is of particular note that *NOV202* is as effective in cancer cells overexpressing the P-glycoprotein transporters which confer multidrug resistance, and is therefore an interesting candidate for second line treatment of P-glycoprotein mediated multidrug resistant tumors. Notably, the clinically used chemotherapeutic drugs, vincristine and paclitaxel, were found to be significantly less potent in the resistant cells as compared to the parental cells.

In vivo efficacy studies in human ovarian cancer xenograft models show that *NOV202* potently suppresses tumor growth, and *in vivo* efficacy studies in mice have shown that *NOV202* was well tolerated when dosed p.o. over a period of up to 26 days, suggesting little off-target toxicity.

In addition, the synthesis of *NOV202* has been optimized and the process developed for large scale production to give high yields and purity. The synthesis is easy and the production costs are low compared to compounds like taxane, vincristine or other compounds that requires several steps in the synthesis. Initial solid state analysis and stability studies have been performed, as well as formulation development work.

NOV202 - Molecular Mechanism of Action

Characterization of *NOV202*, both in cell free systems and in live cells, showed that *NOV202* potently destabilized microtubules. Furthermore, *NOV202* has also been shown to be a potent vascular disrupting agent, causing both inhibition of cord formation, as well as disruption of established cord

structures, at low nanomolar concentrations.

Our data shows that *NOV202* possess dual anti-tumor actions, inducing tumor cell death by G2/M cell cycle arrest and disrupting the tumor blood supply.

Remaining Preclinical Studies up to Phase Ib/IIa Clinical Trials

Large scale synthesis of *NOV202* has been established and the first GLP tox-batch has been manufactured. Remaining studies to clinical trials are GLP-tox and safety studies, and the preparations for these studies are currently ongoing.

Backup Compounds

Noviga's substance library contains several candidates that currently are being evaluated as potential backup candidates for *NOV202*.

Patents and Intellectual Property

Noviga owns the rights to two Patent Families that are at different stages of examination:

Patent Family	Filing Date	Type	Patent Number
1	2011-05-20	PCT *	WO2011144742
2	2012-03-23	PCT **	WO2012127032

*Granted in China, Europe, Japan, USA, allowed in Canada. **Granted in Europe and USA, pending in Canada, China and Japan.

Partnering Objectives

Noviga's objective is to seek an early R&D collaborative partner or Venture funding for further development of the *NOV202* anti-cancer program as second-line therapy in refractory cancers.

Partnering Process & Further Contacts

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