PRESS RELEASE
16 December, 2015

BioInvent update on clinical and preclinical drug programs

Lund, Sweden – 16 December 2015 – BioInvent International (OMXS: BINV) is today providing an update on its clinical and preclinical drug programs. Several positive interactions with regulatory authorities have taken place and clinical trials with three of the Company's antibodies are expected to start in 2016. A scientific advice meeting with the UK Medicines and Healthcare Products Regulatory Agency (MHRA) was held in preparation for the first clinical study of BI-1206. The study plan presented to the regulator, as well as BioInvent's data, were well received. Cancer Research UK plans to submit the Clinical Trial Application in April 2016.

With an increased commitment to the BI-505 program, BioInvent will submit a clinical trial application to the US Food and Drug Administration (FDA) in December 2015.

BioInvent and its partner Oncurios is planning to start a clinical trial with TB-403 in medulloblastoma during early 2016.

BioInvent has established itself as a company with strong clinical programs and a strong position in the immuno-oncology area.

BI-1206
BI-1206 is an antibody that blocks the CD32b protein which is overexpressed in lymphoma (cancer in the lymphatic system). By combining today's standard of care therapy rituximab (Rituxan®/MabThera®) with BI-1206, it is possible to achieve a better anti-tumour effect. The planned Phase I/II clinical study will be sponsored, managed and funded by one of the world's largest scientific non-profit organisations, Cancer Research UK. This is done under an agreement with BioInvent as part of the Clinical Development Partnerships Scheme, a joint initiative between the Centre For Drug Development and Cancer Research Technology.

- In a recent scientific advice meeting with the MHRA, the design of the first clinical study with BI-1206 was discussed. The study will enrol patients with non-Hodgkin lymphoma and chronic lymphatic leukaemia.
- Cancer Research UK plans to submit a Clinical Trial Application for the Phase I/II study to the MHRA in April 2016. The lead clinical site at the University of Southampton and at least three other clinical trial sites in the UK will be involved in the trial and aim to be ready to open to recruitment as soon as all necessary regulatory and ethical approvals are in place.
- In collaboration with leading academic institutions, BioInvent has started preclinical evaluation of BI-1206 against different sub-types of non-Hodgkin lymphoma using human material from biobanks. The results will provide an important basis for designing the continuing clinical programme.

"The meeting with the UK regulatory agency, MHRA, is an important step forward for BI-1206. We have reached an important milestone in this highly innovative program. We are now in a good position to advance this program further towards market registration for carefully selected patient cohorts with the greatest medical need," **says Michael Oredsson, CEO of BioInvent.**

BI-505
BI-505 is a human antibody against ICAM-1 developed by BioInvent, which will be clinically tested in cooperation with researchers at Penn Medicine as an immuno-oncological therapy to prevent or delay relapse in patients with multiple myeloma (a form of bone marrow cancer) undergoing stem-cell transplantation. Preclinical data indicates improved activity against myeloma when BI-505 is administered in combination with Velcade® or Revlimid®. BI-505's favourable safety profile has been demonstrated in a previous phase I trial. This and the unique mechanism of action, "flagging" remaining myeloma cells for elimination by actively recruited macrophages, as well as the potential to

inhibit ICAM-1 dependent survival signals between myeloma cells and tumour stroma, indicate a unique possibility of improving the therapeutic effect of stem-cell transplantation.

- Bioinvent plans to submit an application to the FDA in the USA, requesting to start the randomised, controlled phase II study on multiple myeloma patients undergoing autologous stem-cell transplantation, by December 2015 with Penn Medicine as the coordinating site.
- The study is expected to start in the first quarter of 2016, which is in line with previous communication.
- BioInvent has decided to assume overall responsibility for the study as sponsor of the trial. This will improve control of data and enable expansion of the trial to additional sites, if required.

“By taking on overall responsibility and increasing the number of trial centres for the study with BI-505 we can generate data of the quality required by authorities to enter into discussions regarding a registration procedure based on successful phase II data,” **says Anna Teige Wickenberg, Vice President Clinical Development, BioInvent.**

TB-403
BioInvent and its partner Oncurious are planning to start a new clinical study with the antibody TB-403 against certain rare forms of cancer in the brain, nervous system and connective tissue in children and adolescents. TB-403 has already been evaluated in clinical studies in adults for other cancers and has demonstrated a good safety profile. The project’s new direction is based on new knowledge about the antibody’s mechanism of action. BioInvent has the right to 40 percent of all future revenue from the project.

- The study, which is expected to start in early 2016, will be implemented in cooperation with a network of specialist clinics in the USA with good access to the relevant patient cohorts.
- The preparations for study start are well underway.
- The first safety evaluation part of the study includes patients with medulloblastoma (tumour in the cerebellum), neuroblastoma (tumour in the sympathetic nervous system), Ewings sarcoma (tumour in the connective tissue) and alveolar rhabdomyosarcoma (tumour in the connective tissue), whereas children with medulloblastoma will be included in the efficacy evaluation part of the study.

“Children who suffer from these serious cancers are in great need of more effective treatment and we have therefore prioritised designing a study that should give us the answer as to whether TB-403 is effective in children with medulloblastoma,” **says Michael Oredsson, CEO of BioInvent.**

REGULATORY T-CELLS (TREG)
Regulatory T-cells (Tregs) have a strong ability to inhibit various immune responses. A series of clinical studies show that antibodies targeting CTLA-4 and PD-1 can induce a very long-lasting response in some cancer patients. BioInvent’s F.I.R.S.T™ technology platform is an excellent tool for identification of both target structures and antibodies in the Treg area.

- BioInvent has succeeded in identifying high-affinity antibodies with depleting activity against regulatory T-cells
- A first pool of mouse-reactive anti-Treg antibodies, which can be screened in well- established preclinical models to identify novel targets particularly suitable for antibody-mediated Treg depletion, or modulation of Treg immune suppressive activity, have been identified. Target: antibody pairs will be used to evaluate new drug targets and antibody mechanism-of-action in preclinical proof-of-concept tests, paving way for human cross-reactive, or functionally equivalent human lead clinical candidate antibodies. BioInvent recently announced that the Company has received a non-exclusive licence for a special type of antibody format, IgG2B. Preclinical trials with IgG2B antibodies have shown that this antibody type has the potential to more independently activate immune cells e.g. macrophages and T cells to promote anticancer immune responses. When targeted to appropriate receptors, the IgG2b isotype is expected to increase chances of developing new effective drugs in the immune-oncology area.

OX-40
BioInvent is working in cooperation with Cancer Research Technology (CRT) and the University of Southampton in the UK to develop new immunotherapeutic cancer drugs based on antibodies that target OX-40 and 4-1BB, two known co-receptors that help activate T-cells and long-lasting antitumor immune responses.

- Antibodies with high affinity, agonistic activity on effector T-cells and the ability to eliminate regulatory T-cells in vitro have been generated.
- Preclinical *in vivo* studies to document proof-of-concept for BioInvent's antibodies in the OX-40 project will be initiated during the first quarter of 2016.

TUMOUR ASSOCIATED MYELOID CELLS (TAM)
Myeloid cells are essential to our innate immune system, but they can also be "hijacked" by tumours to support growth and cancer spread. In the fourth quarter of 2015, BioInvent worked on preparations to develop function-modulating antibodies against tumour associated myeloid cells (TAM), a type of white blood cell that is recruited by cancer cells to sustain growth and spread, and prevent immune attack. Antibody-mediated "reprogramming" of immune-suppressive tumour-associated myeloid cells into anti-tumor effector cells is therefore a very attractive therapeutic concept and represents an area of research in which BioInvent and its partners are at the cutting edge.

"F.I.R.S.T is a unique platform to identify new antibody-based drugs that more specifically destroy, or transform, cancer-driving immune cells such as Treg and TAM. Preclinical data indicates that antibodies against Treg and TAM can significantly improve the effects of the immunotherapies available today and make it possible to treat cancers where current immunotherapies aren't working due to a strongly suppressed immune response to the cancer," **says Björn Frendéus, Chief Scientific Officer, BioInvent.**

To the editors:

About BioInvent
BioInvent International AB develops immune oncology drugs. With one of the world's largest antibody libraries, and a unique, proprietary discovery method, BioInvent can identify the optimal cellular targets and antibodies for the treatment of various tumor types. BioInvent has also considerable experience in and a facility for process development and production of antibodies for clinical studies. This makes it possible to develop proprietary drug projects, but also to supply leading international pharmaceutical companies with effective tools for their drug development. BioInvent currently has three proprietary projects in or close to clinical development and partnership agreements with seven global pharmaceutical and biotech companies. More information is available at www.bioinvent.com.

For further information, please contact:
Michael Oredsson
President and CEO
+46 (0)46 286 85 67
+46 (0)70716 89 30
michael.oredsson@bioinvent.com

BioInvent International AB (publ)
Co. reg. No: 556537-7263
Visiting address: Sölvegatan 41
Mailing address: 223 70 LUND
Phone: +46(0)46 286 85 50
info@bioinvent.com
www.bioinvent.com

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