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PRESS RELEASE

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MOLOGEN's presentations well received at ESMO 2017

- Oral presentation of top-line IMPULSE data including invited expert discussion
- Poster presentation of new data on lefitolimod as modulator of the tumor microenvironment alone and in combination with immune checkpoint inhibitors in pre-clinical tumor models

Berlin, 13 September 2017 – **The biopharmaceutical company MOLOGEN AG (ISIN DE0006637200; Frankfurt Stock Exchange Prime Standard: MGN) presented two sets of data on its lead compound, the immunotherapeutic agent lefitolimod, at the European Society for Medical Oncology (ESMO 2017) in Madrid (8 – 12 September 2017). The coordinating investigator Prof. Dr. Michael Thomas, MD, Head of the Department Oncology/Internal Medicine at the Thorax Clinic at University of Heidelberg, Germany, gave an oral presentation on the top-line data from the exploratory, signal-seeking phase II IMPULSE trial in extensive-disease small-cell lung cancer in a *Proffered Paper Session* with the session's co-chair, Prof. Sanjay Popat, The Royal Marsden Hospital, London, acting as invited discussant. Furthermore, data on lefitolimod as modulator of the tumor microenvironment (TME) alone and in combination with immune checkpoint inhibitors in pre-clinical tumor models were presented in the *Translational Research Poster Session*.**

Promising overall survival signal in pre-defined subgroups of IMPULSE

The exploratory randomized IMPULSE study which evaluates the efficacy and safety of lefitolimod in patients with extensive-disease small-cell lung cancer (SCLC) showed noteworthy results in the primary analysis regarding overall survival (OS) in two clinically relevant subgroups of patients in comparison to the control group (standard therapy). A signal for an OS benefit was seen in patients with reported Chronic Obstructive Pulmonary Disease (COPD), a frequent underlying disease.

Notably, a strong OS signal was observed in patients with a low count of activated B cells, an important immune parameter, at baseline. This contributes to the hypothesis that activated B cells may serve as a valid biomarker in the further development of lefitolimod in this relevant subgroup

of extensive-disease SCLC patients. The invited discussant Prof. Popat interpreted IMPULSE as a signal-generating study with an interesting hypothesis which merits further evaluation.

"To our knowledge IMPULSE is the first randomized controlled clinical study of a maintenance therapy following first-line chemotherapy in extensive-disease SCLC showing a promising overall survival signal in a pre-specified subgroup. The study provides important guidance for defining patient populations most likely to benefit from treatment with lefitolimod in further clinical trials," said Dr. Matthias Baumann, Chief Medical Officer of MOLOGEN AG. "I am also delighted that the European Thoracic Oncology Platform (ETOP) asked Prof. Thomas for permission to publish his presentation on their website which, in our view, underlines the interest of the scientific community in our approach."

Lefitolimod-induced modulation of the tumor microenvironment supports its potential as ideal partner for immune-oncology combination therapies

The lefitolimod-induced pathway provides the rationale for combining lefitolimod with checkpoint inhibitors (CPI). First combination data of lefitolimod with checkpoint inhibitors in mouse tumor models have been presented at the Annual 2017 Gastrointestinal Cancers Symposium in San Francisco, USA (January 19-21, 2017). The data showed that lefitolimod can significantly improve the anti-tumor effect of checkpoint inhibitors, particularly anti-PD-1 and anti-PD-L1 antibodies, and thus prolong survival in murine colon carcinoma and lymphoma tumor models.

Response rates to checkpoint inhibitor immunotherapy vary between different tumor entities and depend on the nature of the tumor microenvironment (TME). Hot tumors with a T cell-infiltrated TME show better responses. Therefore, modulation of the TME is a crucial requirement for the response to immunotherapeutic approaches.

MOLOGEN's current data showed that monotherapy with lefitolimod resulted in a modulation of the TME in a colon carcinoma tumor model after intra-tumoral injection. An increased infiltration of T cells, especially cytotoxic T cells, into the tumor was shown, which was associated with reduced tumor growth. This beneficial modulation of the TME by lefitolimod supports its potential in cancer immunotherapy. Hence, lefitolimod may be an ideal partner for immune-oncology combination approaches, i.e. with checkpoint inhibitors.

Background to the IMPULSE small-cell lung cancer (SCLC) study

The trial titled "*Randomized Clinical Study of Maintenance Therapy with **I**mmunomodulator **M**GN1703 in **p**atients with Extensive Disease Small Cell L**u**ng Cancer after Pl**a**tinum-Ba**se**d First-Line Therapy*" (IMPULSE study) is an explorative study and has overall survival as the primary endpoint. It compares lefitolimod (MGN1703) versus standard therapy (chemotherapy). The study included 102 patients suffering from extensive-disease small-cell lung cancer and showing at least partial response to four cycles of first-line chemotherapy. They were randomized at a ratio of 3:2 to switch-maintenance therapy with lefitolimod (60mg injected subcutaneously twice weekly) or standard therapy until disease progression.

There will be a final read-out probably in the first quarter of 2018, approximately 24 months following the recruitment of the last patient.

Further information can be found on MOLOGEN's website:
www.mologen.com

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MOLOGEN AG is a biopharmaceutical company and considered a pioneer in the field of immunotherapy on account of its unique active agents and technologies. Alongside a focus on immuno-oncology, MOLOGEN AG develops immunotherapies for the treatment of infectious diseases.

The immunotherapy lefitolimod (MGN1703) is the company's lead product and is regarded as the best-in-class TLR9 agonist. Treatment with lefitolimod triggers a broad and strong activation of the immune system. In contrast to other TLR9 approaches lefitolimod is exclusively composed of natural DNA and may therefore be less prone to non-specific side effects and exhibits a broad therapeutic window, which allows for both, systemic treatment (i.e. subcutaneous injection) and intra-tumoral administration. On account of this mode of action, lefitolimod (MGN1703) is an immune surveillance reactivator (ISR) and could potentially be used in various indications. The ISR lefitolimod (MGN1703) is currently being developed within the framework of a pivotal study for first-line maintenance therapy for colorectal cancer. The phase II IMPULSE study in small cell lung cancer is showing positive results in two previously defined and clinically relevant patient sub-groups, even though the primary endpoint "Overall Survival" in the overall study population was not met in this very challenging indication. Detailed analyses of IMPULSE data and the recently published TEACH data of the extension phase are currently being conducted. In addition, lefitolimod (MGN1703) is currently being investigated in a phase I combination study with the checkpoint inhibitor ipilimumab (Yervoy®) in various cancer indications. Alongside with various

checkpoint inhibitors, lefitolimod, which is being investigated as part of a phase III clinical trial currently, is one of the few near-to-market product candidates in the field of immuno-oncology.

MOLOGEN's pipeline focus is on new innovative immunotherapies to treat diseases for which there is a great medical demand in particular.

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Contact

Claudia Nickolaus

Head of Investor Relations & Corporate Communications
Tel: +49 - 30 - 84 17 88 - 38
Fax: +49 - 30 - 84 17 88 - 50
investor@mologen.com

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