Pressmeddelande 7 november 2011

Medivirs partner Tibotec meddelar att slutliga SVR24-resultat från fas IIb-studien PILLAR med TMC435 kommer att presenteras idag på AASLD-mötet

Huddinge - Medivir AB (OMX:MVIR), det forskningsbaserade specialistläkemedelsbolaget som fokuserar på utveckling av högkvalitativ behandling av infektionssjukdomar, noterar att bolagets utvecklingspartner Tibotec Pharmaceuticals offentliggör säkerhets- och effektdata från fas IIb-studien PILLAR, som omfattar behandling av behandlingsnaiva HCV-patienter med TMC435 en gång dagligen. Slutresultatet kommer att presenteras idag vid en muntlig så kallad late breaker-presentation på AASLD-mötet i San Francisco, USA.

Tibotec gjorde följande uttalande den 5 november 2011:

Tibotec to present final safety and efficacy results from phase 2b PILLAR study of Once-daily TMC435 in late-breaker at AASLD

-- Data show high rates of virologic response and shortened treatment duration; safety and tolerability comparable to placebo --

[San Francisco, CA. Saturday 5th November 2011] – Tibotec Pharmaceuticals (Tibotec), one of the Janssen (Janssen) Pharmaceutical Companies, today will present results of the final analysis of PILLAR, a phase 2b study of the investigational hepatitis C virus (HCV) NS3/4A protease inhibitor TMC435 in treatment-naïve patients with chronic genotype 1 HCV, as part of a late-breaker oral presentation at the 62nd Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in San Francisco, CA, USA.

Results from the final PILLAR analysis showed that TMC435 administered in combination with peginterferon α-2a and ribavirin (PR) resulted in significantly higher sustained virologic response (SVR) rates compared to placebo plus PR. In the two TMC435 treatment groups who received TMC435 75mg, between 75 and 82 percent of patients achieved SVR24, and in the two TMC435 treatment groups who received TMC435 150mg, between 81 and 86 percent of patients achieved SVR24. This is compared to 65 percent of patients in the placebo arm who achieved SVR24. In addition, 79 to 86 percent of patients in the TMC435 treatment arms had a shortened treatment duration of 24 weeks, compared to a 48 weeks treatment duration for patients who received placebo plus P/R. In TMC435 arms, 68 to 76 percent of patients achieved rapid virologic response [RVR; HCV RNA<25 (undectectable)], of whom 88 to 95 percent achieved SVR24. There were no significant differences for adverse events between TMC435 treatment groups and placebo. TMC435 150mg administered once daily (q.d.) is being investigated in phase 3 trials in treatment-naive patients and in patients who experienced a viral relapse after being treated with interferon-based therapy. TMC435 is being developed by Tibotec Pharmaceuticals. Medivir AB has commercialization rights for TMC435 for the Nordic countries, Janssen has commercialization rights for TMC435 in the rest of the world.

*The PILLAR study [**P**rotease **I**nhibitor TMC435 trial assessing the optima**L** dose and duration as once dai**L**y **A**nti-viral **R**egimen] (TMC435-C205; NCT00882908) was a five-arm, global phase 2b randomized, double-blind, placebo controlled study in 386 treatment-naive patients. TMC435 was administered in doses of 75mg or 150mg q.d. for either 12 weeks or 24 weeks in combination with 24 or 48 weeks of peg-interferon and ribavirin (PR). Patients in the placebo arm receive 24 weeks of*

placebo plus peg-interferon and ribavirin followed by 24 additional weeks of peg-interferon and ribavirin treatment. The primary endpoint of the study was sustained virologic response at Week-72 (SVR week 72). The PILLAR study was conducted in 13 countries in Europe, North America, and Australasia.

Patients receiving TMC435 were allowed to stop all treatment at week 24 if they met both response-guided criteria: a) detectable or undetectable HCV RNA levels (< 25 IU/mL) at week 4 and b) undetectable HCV RNA at weeks 12, 16 and 20. Patients who did not meet the above response-guided criteria continued with peg-interferon and ribavirin until Week-48.

"HCV is a devastating problem worldwide and remains a leading cause of cirrhosis, liver cancer, and liver transplantation," said Dr. Michael W. Fried M.D., lead clinical investigator and Professor of Medicine, Director, UNC Liver Center, University of North Carolina at Chapel Hill. "We are extremely encouraged by the success of once-daily TMC435 in achieving significantly higher SVR compared to control group and look forward to furthering its development in recently launched phase 3 trials."

The goal of HCV treatment is to achieve SVR24, which means the virus is undetectable in patients' blood six months after they have finished treatment. Patients who achieve SVR are considered cured.

The most common adverse events (AEs) in the PILLAR study were headache and fatigue, 46 percent and 42 percent in the TMC435 groups and 51 percent and 47 percent in the placebo group respectively. There were no clinically significant differences in frequency of rash, anemia or gastrointestinal events between the TMC435 groups and placebo. Most AEs were mild to moderate in severity. AEs leading to treatment discontinuation of TMC435/placebo were reported in 7.1 percent of patients in TMC435 arms and 7.8 percent in placebo arm.

"Tibotec is pleased to present the final results of the phase 2b PILLAR study at AASLD. The continued development of TMC435, which is currently being investigated in registrational phase 3 studies, reinforces our strong commitment to the development of new therapies that may reduce treatment duration and improve the lives of those impacted by HCV," said Maria Beumont M.D., Global Medical Leader TMC435 at Tibotec.

In conjunction with the final sustained virologic response (SVR) results from PILLAR, Tibotec is presenting virology analysis data from PILLAR and two sets of early study results on the effects of co-administering TMC435 and methadone and its interaction with the antidepressant escitalopram, to be featured in 3 posters at AASLD:

- *"TMC435 in combination with peginterferon alpha-2a/ribavirin in treatment-naïve patients infected with HCV genotype 1: virology analysis of the PILLAR study." O. Lenz.*
- *"The pharmacokinetic interaction between the investigational NS3-4A HCV protease inhibitor TMC435 and methadone." M. Beumont-Mauviel.*
- *"The pharmacokinetic interaction between the investigational HCV NS3/4A protease inhibitor TMC435 and escitalopram." M. Beumont-Mauviel.*

Tibotec is currently conducting two global, phase 3 registrational trials to examine TMC435 in treatment-naïve adults with chronic genotype 1 hepatitis C virus (HCV). A third global phase 3 trial is being conducted in genotype 1 HCV patients who have experienced a viral relapse after prior interferon-based treatment. All three studies are fully randomized.

- End -

Om TMC435

TMC435 är en mycket potent och selektiv läkemedelskandidat som doseras en gång dagligen. TMC435 utvecklas gemensamt med Tibotec Pharmaceuticals för behandling av kroniska hepatit C-virusinfektioner.

TMC435 har beviljats snabbehandling, så kallad Fast Track, av amerikanska läkemedelsmyndigheten FDA för behandling av kronisk hepatit C-virusinfektion (CHC) av genotyp 1. Detta baseras på TMC435s potential att svara mot tidigare ouppfyllda medicinska behov i behandlingen av kronisk HCV-infektion. TMC435 utvecklas för närvarande i tre globala fas III-studier, QUEST-1 och QUEST-2 för behandlingsnaiva patienter, och PROMISE för patienter som återinsjuknat efter tidigare genomgången interferonbaserad behandling. Parallellt med dessa studier pågår fas III-studier med TMC435 i Japan, med både behandlingsnaiva och behandlingserfarna patienter infekterade med hepatit C av genotyp 1.

För ytterligare information om dessa studier, vänligen se www.medivir.com och www.clinicaltrials.gov

För mer information om Medivir, vänligen kontakta:
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Om hepatit C
Hepatit C är en blodburen infektionssjukdom som drabbar levern och den vanligaste orsaken till kronisk leversjukdom och levertransplantation. Världshälsoorganisationen uppskattar att nära 180 miljoner människor världen över, eller cirka tre procent av världens befolkning, är infekterade med hepatit C-viruset (HCV). Enligt CDC har nära tre miljoner människor i USA en kronisk HCV-infektion.

Om Medivir
Medivir är ett växande forskningsbaserat specialistläkemedelsbolag som fokuserar på behandling av infektionssjukdomar inom värdemässigt stora sjukdomsområden. Medivir har expertis av världsklass på området polymeraser och proteasenzymer som läkemedelsklasser samt när det gäller läkemedelsutveckling inom detta område, vilket har resulterat i en bred FoU-portfölj inom området infektionssjukdomar. Bolagets nyckelproduktkandidat är TMC435, en proteashämmare som är i klinisk fas 3-utveckling för behandling av hepatit C. TMC435 utvecklas i samarbete med Tibotec Pharmaceuticals.

I juni 2011 förvärvade Medivir specialistläkemedelsbolaget BioPhausia i syfte att kommersialisera TMC435 på de nordiska marknaderna när läkemedlet blir godkänt.

Medivirs första produkt, den unika munsårsprodukten Xerese®/Xerclear®, lanserades på den amerikanska marknaden i februari 2011. Xerese®/Xerclear®, som är godkänt både i USA och Europa, lanseras i samarbete med GlaxoSmithKline för receptfri försäljning i Europa, Japan och Ryssland. Rättigheterna i Nordamerika, Kanada och Mexico såldes till Meda AB i juni 2011. Medivir har behållit rättigheterna för försäljning av Xerclear® i Sverige och Finland.

För mer information om Medivir, vänligen se bolagets webbplats: **www.medivir.com**