Novartis marks 30 year anniversary in transplantation and reinforces continued commitment to organ recipients at ESOT congress

- Novartis reaffirms continued innovation in transplant during anniversary year of breakthrough therapy, ciclosporin
- TRANSFORM trial to be presented: largest ever study of its kind, evaluating Certican® (everolimus) in more than 2,000 kidney transplant recipients, using innovative novel endpoint
- Breadth of data reinforces efficacy and safety profile of Certican and ongoing commitment to improving transplant patients’ lives in the long-term

Basel, September 4, 2013 – Demonstrating the strength of its ongoing commitment to improve the lives of transplant patients through innovation, Novartis will present 24 abstracts from its portfolio of transplant therapies at the 16th congress of the European Society of Organ Transplantation (ESOT) in Vienna next week. In the year that marks the 30th anniversary of ciclosporin, Novartis will share its latest data addressing the long-term needs of transplant patients1,2. This includes the innovative TRANSFORM study design, a landmark trial investigating long-term outcomes in kidney transplant recipients treated with Certican1.

“Having shaped the transplant landscape from the beginning with the discovery of ciclosporin 30 years ago, we remain committed to developing innovative solutions that advance the care of transplant patients,” said Dr. Timothy Wright, Global Head Development, Novartis Pharmaceuticals.

Novartis’ discovery of the first calcineurin inhibitor (CNI), ciclosporin, was a watershed moment in the history of organ transplantation3. Following its approval 30 years ago, ciclosporin improved the one-year kidney graft survival rate from around 50% to more than 80%4 and CNIs remain the most effective and widely used immunosuppressive agents in organ transplantation today5.

About Certican and the TRANSFORM study1
The landmark TRANSFORM trial is an innovative long-term outcomes study with the potential to change the treatment paradigm for preventing rejection in de novo (first-time) kidney transplant recipients. For the transplant patient, it is no longer just about surviving; it is about living a long and fulfilling life thanks to improved outcomes (reduced risk of mortality and cardiovascular (CV) events, and improved quality of life).

Novartis is committed to improving the lives of patients in the long-term through investment in innovative clinical trials like TRANSFORM, which it is hoped will be at the forefront of the next major evolutionary shift in transplantation.

This global, Phase IV study, the largest ever in de novo kidney transplantation, is designed to evaluate the short- and long-term benefits of Certican plus low dose CNIs in
kidney transplantation. The study of more than 2,000 patients will investigate de novo Certican + low dose CNI versus Mycophenolic Acid (MPA) + standard CNI, evaluating renal function and graft outcomes at 12- and 24- months, as well as long-term outcomes up to five years.

The TRANSFORM trial is the first ever kidney transplantation study to evaluate the short- and long-term patient outcome benefits using an innovative and novel endpoint that combines renal function and graft outcome.

Novartis transplant portfolio highlights at ESOT, 8-11 September 2013

Certican in kidney transplant

- The HERAKLES study at 24 month: superior renal function in an everolimus-based CNI-free regimen. O219, Guba, 10 September, 11:20 hrs CEST
- Safety of everolimus in kidney and liver transplantations: does the organ matter? BO262, Kohler, 10 September, 16:05 hrs CEST
- Longer-term efficacy and safety of everolimus in de novo renal transplant recipients. BO145, Watarai, 9 September, 16:20 hrs CEST
- 5-year follow-up on the ZEUS KTx trial: everolimus conversion after CNI withdrawal. BO142, Lehner, 9 September, 16:05 hrs CEST
- HERAKLES at month 24: efficacy and safety of 3 different regimens in de novo renal transplant patients. BO148, Lehner, 9 September, 16:35 CEST
- 12-month outcomes from EVIDENCE trial (Everolimus once-a-day regimen with cyclosporine versus corticosteroid elimination) in adult kidney transplant recipients. O193, Guarisco, 10 September, 8:20 hrs CEST
- Design of CRAD001A2314: a randomised study evaluating everolimus in pediatric renal transplantation. P712, Tönshoff, 8 September, 18:15 - 19:30 hrs CEST
- Search for new endpoints for clinical trials of immunosuppressive drugs in kidney transplantation. P312, Tedesco-Silva, 8 September, 18:15 - 19:30 hrs CEST
- TRANSFORM trial design: effect of everolimus on long-term outcomes after kidney transplantation. P308, Pascual, 8 September, 18:15 - 19:30 hrs CEST
- Outcome on renal function of everolimus conversion in maintenance KTx patients: 4 years APOLLO trial. P271, Rhat, 8 September, 18:15 - 19:30 hrs CEST

Certican in liver and non-kidney transplant

- Sustained better renal function with everolimus and reduced tacrolimus in liver transplantation. BAC04 (Abstract Challenge Presentation) BAC - Best Abstract Challenge, Saliba, 9 September, 11:40 hrs CEST
- mTOR inhibition and evolution of urinary protein excretion in non-renal transplant recipients. O192, Junge, 10 September, 08:10 hrs CEST
- Efficacy and safety of everolimus-facilitated tacrolimus reduction versus standard tacrolimus. O277, De Simone, 10 September, 17:20 hrs CEST
- A rational approach to quantify the mTOR treatment effect in liver transplant recipients. O194, Junge, 10 September, 08:30 hrs CEST
- The PROTECT Study: sustained superior renal function in liver transplant recipients after 35 months with everolimus monotherapy vs. calcineurin inhibitor-based therapy. O275, Sterneck, 10 September, 17:00 hrs CEST
- Early calcineurin inhibitors avoidance improves renal function in de novo heart transplant recipients: the results of a randomized controlled trial (SCHEDULE trial) O076, Gude, 9 September, 11:40 hrs CEST
- Long-term therapy with everolimus in heart transplant recipients: two-years results of the CERTIC Registry. O195, Brusa, 10 September, 8:40 hrs CEST
- Cardiovascular events with de novo use of everolimus in heart transplant recipients. O073, Potena, 9 September, 11:10 hrs CEST
• Early vs delayed everolimus introduction in heart transplantation: analysis of safety on the first 100 patients of the EVERHEART study. BO225, Boffini, 10 September, 16:15 hrs CEST
• Design of the H2307 study: everolimus with reduced tacrolimus in living donor liver transplantation. P571, Junge, 8 September, 18:15 - 19:30 hrs CEST
• Design of H2305: a prospective study evaluating everolimus in pediatric liver transplantation. P717, Ganschow, 8 September, 18:15 - 19:30 hrs CEST

Pipeline and additional data
• Drug-drug interaction assessment to guide optimal use of hepatitis c antivirals with immunosuppressants. P066, Barve, 8 September, 18:15 - 19:30 hrs CEST
• Efficacy and safety of the pkc-inhibitor sotrastaurin in de novo liver transplant recipients. O278, Pascher, 8 September, 19:30 hrs CEST
• Progression of fibrosis in HCV+ liver transplant recipients treated with cyclosporine or tacrolimus. O279, Nevens, 10 September, 17:40 hrs CEST

About Certican (everolimus)
Everolimus is one of the most-extensively studied immunosuppressants in solid organ transplantation with more than 10,000 transplant recipients enrolled in Novartis-sponsored clinical trials worldwide. Under the trade name Certican®, it is approved in more than 90 countries to prevent organ rejection for renal and heart transplant patients, and in addition, is approved in the EU and other countries worldwide to prevent organ rejection for liver transplant patients. In the U.S., under the trade name Zortress®, the drug is approved for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant, and is also approved in adult patients following a liver transplant.

Everolimus is also available from Novartis in different dosage strengths and for different uses in non-transplant patient populations under the brand names Afinitor® and Votubia®. It is also exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Not all indications are available in every country. As an investigational compound, the safety and efficacy profile of everolimus has not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for additional indications anywhere else in the world.

Disclaimer
The foregoing release contains forward-looking statements that can be identified by terminology such as “continued,” “commitment,” “ongoing,” “will,” “committed,” “potential,” “hope,” “designed to,” or similar expressions, or by express or implied discussions regarding potential new indications or labeling for everolimus or regarding potential future revenues from everolimus. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with everolimus to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that everolimus will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that everolimus will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding everolimus could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; unexpected manufacturing issues; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general;
government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis
Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 131,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

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References
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Novartis Media Relations

Central media line: +41 61 324 2200
Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Barbara Duci
Novartis Global Pharma Communications
+41 61 324 0285 (direct)
+41 79 701 7982 (mobile)
barbara.duci@novartis.com

e-mail: media.relations@novartis.com

For Novartis multimedia content, please visit www.thenewsmarket.com/Novartis
For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone: +41 61 324 7944
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425

North America:
Stephen Rubino +1 862 778 8301
Jill Pozarek +1 212 830 2445