# **News**Room

8/30/00 PA Wire 00:00:00

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August 30, 2000

### **MEDICAL Novartis**

#### NOVARTIS ANNOUNCES POSITIVE TRIAL RESULTS FOR TWO NOVEL TRANSPLANTATION DRUGS

:: PR Newswire, London, August, 30. This press release is transmitted on behalf of Novartis.

Rome, Italy - At the 18th International Congress of the Transplantation Society Novartis presented encouraging data today from two series of trials on Certican (everolimus) (RAD) and on FTY720, two new transplant drugs, that are designed to reduce the incidence of acute rejection following organ transplantation.

Certican is a novel proliferation signal inhibitor (PSI) designed to protect transplant recipients from acute and chronic rejection and from the toxicities of conventional agents. Certican, currently in Phase III clinical development, has been studied in more than 3,200 patients and found to be an effective and generally safe immunosuppressive agent. Certican is expected to hold the promise to reduce chronic rejection by affecting the mechanism associated with vascular rejection and by inhibiting growth-factor driven smooth muscle cell proliferation.

"As we continue to refine our clinical understanding of immunosuppression, our goal is to provide new therapeutic options that reduce the risk of organ rejection and enhance long-term outcomes for transplant recipients," said Drummond Paris, Global Head of the transplantation business at Novartis. "These data demonstrate the advances Novartis is making in novel anti-rejection therapies."

In addition, Certican may offer the potential to reduce concomitant medications such as steroids. Certican is being developed to be used with Neoral and was well tolerated in clinical studies up to doses of 5 mg/day. Safety and preliminary efficacy studies of Certican in de novo renal transplant patients at six months demonstrated Certican as a potent immunosuppressant that is well tolerated with a low rate of opportunistic infections.

FTY720 is a novel immunosuppressant with a unique mechanism of action, currently in Phase II pre-clinical trials. In vivo studies of FTY720 demonstrate its ability to prolong allograft survival with remarkable potency. Very recent data show that extrapolated to the transplantation situation, the intact immunity to systemic infection during treatment with FTY720 may provide a striking advantage compared to classical immunosuppressive agents.

FTY720 has been shown to efficiently prevent rejection of solid organ grafts. Furthermore, it has been shown that combined treatment with FTY720 plus Neoral prolongs cardiac allograft survival in preclinical studies. The molecule shows synergy with Neoral+Certican, suggesting the potential for use in multi-drug combinations.

:: Additional Novartis advances in transplant therapies



ERL is an advanced enteric-coated IMPDH (inosine monophosphate dehydrogenase) inhibitor designed to provide improved gastrointestinal (GI) tolerability which would allow maintenance of potent therapeutic dosing. Continuous therapeutic dosing will potentially lead to better long-term outcomes for patients. Studies are underway to explore a potential GI benefit over mycophenolate mofetil (MMF). This may represent a significant advance over MMF since approximately one-third of MMF patients suffer from GI complications. ERL is currently in Phase III clinical development.

Novartis also presented data from two new studies that demonstrate that changing the procedures used for monitoring blood levels of Neoral, the most widely-used immunosuppressant therapy among liver and kidney transplant recipients, significantly reduces the incidence of acute rejection. The studies show that measuring Neoral blood levels two hours post-dosage (C2) as opposed to the conventional trough (C0) monitoring, improved clinical outcomes without raising the incidence of adverse events. These findings have broad application to the transplant community worldwide.

The foregoing press release contains forward-looking statements that can be identified by terminology such as "demonstrated in studies," "designed to ," "shows," "is expected to," "potentially," "may" or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance, or achievements expressed or implied by such statements. In particular, management's expectations regarding the above mentioned products, as well as future development results, could be affected by, among other things, uncertainties relating to clinical trials and product development; unexpected regulatory actions or government regulation generally; the company's ability to obtain or maintain patent and other proprietary intellectual property protection; and competition in general.

#### :: About Novartis

Novartis is a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health. In 1999, the Novartis Group (including Agribusiness) achieved sales of CHF 32.5 billion and invested more than CHF 4.2 billion in R&D. Headquartered in Basel, Switzerland, Novartis employs about 82,400 people and operates in more than 140 countries around the world. In July 2000, a novel organizational structure for the Group's pharmaceutical operations was unveiled. The new entities-"Primary Care," "Specialty Businesses" and "Mature Products"-wil

create focused and entrepreneurial business units and integrate all critical business functions. The Group most recently announced plans to spin off its Crop Protection and Seeds sectors and to merge them with the agrochemical business of AstraZeneca in the second half of 2000.

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Company: NOVARTIS AG; ASTRAZENECA PLC

News Subject: (Legal (1LE33); Technology Law (1TE30); Major Corporations (1MA93))



Industry: (Pharmaceuticals & Biotechnology (1PH13); Clinical Outcomes (1CL11); Healthcare Services (1HE13); Surgery (1SU58); Manufacturing (1MA74); Transplantation (1TR43); Healthcare (1HE06); Healthcare Cost-Benefits (1HE10); Healthcare Practice Specialties (1HE49); Surgical Specialties (1SU42))

Region: (Western Europe (1WE41); Europe (1EU83); Central Europe (1CE50); Switzerland (1SW77))

Language: EN

Other Indexing: (18TH INTERNATIONAL CONGRESS; ASTRAZENECA; ERL; GI; MMF; NOVARTIS; NOVARTIS GROUP; RUDER FINN PUBLIC; SEEDS; TRANSPLANTATION SOCIETY) (Additional Novartis; Certican; Global Head; MEDICAL Novartis; Novartis; Philippa Jones; Primary Care)

Word Count: 1150

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