Data on Investigational Drug Belatacept in Kidney Transplant Recipients to Be Presented at 23rd International Congress of The Transplantation Society

Release Date: Saturday, August 14, 2010 9:08 am EDT

Terms: R&D News

Dateline City: PRINCETON, N.J.

Seven Clinical Abstracts to be Presented Orally, Including Two-Year Phase 3 Data

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) announced today that belatacept, an investigational selective T cell co-stimulation blocker being studied for use in solid organ transplantation, will be the subject of seven oral clinical presentations related to kidney transplantation at the 23rd International Congress of The Transplantation Society, being held August 15–19, 2010, in Vancouver, British Columbia, Canada. In total, 18 abstracts from company-sponsored studies will be presented during the congress.

Belatacept is currently under review with the U.S. Food and Drug Administration (FDA), as well as the European Medicines Agency (EMA) and other health authorities, for use in adult patients receiving kidney transplants. On May 1, 2010, Bristol-Myers Squibb received a complete response letter from the FDA requesting 36-month data from the ongoing Phase 3 studies to further evaluate the long-term effect of belatacept. The company is working with the FDA to provide that data, as well as answer some requests for information to support the manufacturing of belatacept and the proposed Risk Evaluation and Mitigation Strategy (REMS) program.

“Bristol-Myers Squibb is pleased to present data, including our two-year Phase 3 data on belatacept, at this international congress,” said Brian Daniels, M.D., senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. “We are committed to the development of this compound as a potential therapeutic option for kidney transplant patients.”

The seven belatacept oral clinical presentations related to kidney transplantation are as follows:

<table>
<thead>
<tr>
<th>Date and Time</th>
<th>Presentation Title</th>
<th>Lead Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>O26.05 Session Info: Oral Sessions, [O26] New Immunosuppressive Agents Day/Date: Tuesday, August 17, 2010 Session Time: 10:30 AM - 12:00 PM Room: Ballroom A/B</td>
<td>Belatacept vs Cyclosporine in Kidney Transplant Recipients: Two-Year Outcomes from the BENEFIT Study</td>
<td>C. Larsen Emory University Atlanta, GA</td>
</tr>
<tr>
<td>O26.04 Session Info: Oral Sessions, [O26] New Immunosuppressive Agents Day/Date: Tuesday, August 17, 2010 Session Time: 10:30 AM - 12:00 PM Room: Ballroom A/B</td>
<td>Belatacept vs Cyclosporine in ECD Kidney Transplants: Two-Year Outcomes from the BENEFIT-EXT Study</td>
<td>A. Durrbach Bicêtre Hospital, Kremlin Bicêtre, France</td>
</tr>
<tr>
<td>O26.02 Session Info: Oral Sessions, [O26] New Immunosuppressive Agents Day/Date: Tuesday, August 17, 2010 Session Time: 10:30 AM - 12:00 PM Room: Ballroom A/B</td>
<td>Immunosuppression with Belatacept-based, CNI-avoiding and Steroid-avoiding Regimens vs a Tacrolimus-based, Steroid-avoiding Regimen in Kidney Transplant Patients: Results of a 1-year, Randomized Study</td>
<td>R. Ferguson Ohio State Univ. College of Medicine Columbus, OH</td>
</tr>
</tbody>
</table>
Day/Date: Tuesday, August 17, 2010
Session Time: 10:30 AM - 12:00 PM
Room: Ballroom A/B
Switch From a CNI- to a Belatacept-Based Immunosuppressive Regimen in Kidney Transplant Recipients is Safe and Results in Better Renal Function: 12 Month Results from a Phase II Study
L. Rostaing
Univ. Hospital Toulouse, France

O26.01 Session Info: Oral Sessions, [O26] New Immunosuppressive Agents
Day/Date: Tuesday, August 17, 2010
Session Time: 10:30 AM - 12:00 PM
Room: Ballroom A/B
Safety Profile of Belatacept in Kidney Transplant Recipients from a Pooled Analysis of Phase II and Phase III Studies
J. Grinyó
Univ. Hospital Bellvitge Barcelona, Spain

O47.03 Session Info: Oral Sessions, [O47] Clinical Trials of Immunosuppression
Day/Date: Wednesday, August 18, 2010
Session Time: 3:30 PM - 5:00 PM
Room: Ballroom A/B
Outcomes as a Function of Donor Criteria from a Phase III Study of Belatacept vs Cyclosporine in Kidney Transplantation (BENEFIT-EXT)
S. Florman
Mount Sinai Medical Center New York, NY

Day/Date: Tuesday, August 17, 2010
Session Time: 10:30 AM - 12:00 PM
Room: Ballroom C
Outcomes as a Function of Donor: Recipient Characteristics from a Phase III Study of Belatacept vs Cyclosporine in Kidney Transplantation (BENEFIT)
F. Vincenti
Univ. of California San Francisco, CA

About Belatacept
Belatacept is an investigational agent under development by Bristol-Myers Squibb for the prophylaxis of organ rejection in adult patients receiving kidney transplants. The proposed trade name for belatacept is NULOJIX™.

Belatacept is a fusion protein designed to be a selective T cell co-stimulation blocker that binds to a specific site on certain cells of the immune system (i.e., antigen presenting cells) to block the second signal necessary to activate T cells, which are the predominate immune mediators of allograft rejection.

About Bristol-Myers Squibb
Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit http://www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

Bristol-Myers Squibb Forward-Looking Statement
This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding product development. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that belatacept will receive regulatory approval or, if approved, that it will become a commercially successful product. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2009, in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Language:
English

Contact:
Bristol-Myers Squibb Company
Media:
Phil McNamara, 609-252-6022
phil.mcnamara@bms.com
or
Investors:
John Elicker, 609-252-4611
john.elicker@bms.com