New Data from Bristol-Myers Squibb on NULOJIX® (belatacept) to be Presented at the 2011 European Society for Organ Transplantation Congress

Release Date:
Thursday, September 1, 2011 9:00 am EDT

Terms:
R&D News

Dateline City:
PRINCETON, N.J.

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced that new data on NULOJIX (belatacept) will be presented at the European Society for Organ Transplantation (ESOT) Congress on September 4-7, 2011 in Glasgow, Scotland, United Kingdom. In total, 15 abstracts from company-sponsored and supported studies will be presented during the congress, including data from the pivotal trials that supported the recent European Commission Marketing Authorization and U.S. Food and Drug Administration approval of NULOJIX in June, 2011 for the prophylaxis of organ rejection in adult EBV seropositive patients receiving a kidney transplant, in combination with basiliximab induction, mycophenolate mofetil (MMF), and corticosteroids. The breadth of data being highlighted at this key congress reinforces the company's commitment to innovate in the areas of serious disease and biologics drug development.

New data on NULOJIX being presented for the first time include:
- Donor Sub-type Analysis of Three-year Outcomes from a Phase III Study of Belatacept in Recipients of Extended Criteria Donor Kidneys (BENEFIT-EXT Trial)
- Outcomes at 3 Years in Kidney Transplant Recipients with Pre-Transplant Diabetes from Two Phase 3 Belatacept Studies
- Evaluation of Donor-Specific Antibodies in Kidney Transplant Patients Treated with Belatacept- or Cyclosporine-Based Immunosuppression in BENEFIT and BENEFIT-EXT
- A Comparison of the Peripheral Blood mRNA Transcriptional Profile of Belatacept- and Cyclosporine-treated Renal Transplant Patients

"The clinical data on NULOJIX being presented at the European Society for Organ Transplantation Congress will add to the body of research that supported its U.S. and European approvals," said Brian Daniels, M.D., senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. "BMS is committed to work with the transplant community to broaden our understanding of the efficacy and safety profile for NULOJIX which can enable patients and physicians to make informed decisions about treatment options."

The full schedule of clinical presentations at the ESOT Congress is as follows:

<table>
<thead>
<tr>
<th>Session Date and Time</th>
<th>Presentation Title</th>
<th>Lead Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 6, 2011</td>
<td>Three-Year Outcomes from BENEFIT: A Phase III Study of Belatacept vs Cyclosporine in Kidney Transplant Recipients</td>
<td>F. Vincenti San Francisco, CA</td>
</tr>
<tr>
<td>11:10 a.m.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11:20 a.m.</td>
<td>Belatacept Compared with Cyclosporine in Renal Allograft Recipients of Extended Criteria Donor Kidneys: 3-year Outcomes from the Phase III BENEFIT-EXT Trial</td>
<td>A. Durrbach France</td>
</tr>
<tr>
<td>Oral Session 29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clyde Auditorium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>September 6, 2011</td>
<td>3-Year Safety Profile of Belatacept in Kidney Transplant Recipients from the BENEFIT and BENEFIT-EXT Studies</td>
<td>B. Charpentier France</td>
</tr>
<tr>
<td>11:30 a.m.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-242</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral Session 29</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clyde Auditorium</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Outcomes at 3 Years in Kidney Transplant Recipients with Pre-transplant Diabetes from Two Phase 3 Belatacept Studies
L. Rostaing
Toulouse, France

Evaluation of Donor-Specific Antibodies in Kidney Transplant Patients Treated with Belatacept- or Cyclosporine-based Immunosuppression in BENEFIT and BENEFIT-EXT
C. Larsen
Atlanta, GA

Renal Function at 2 Years in Kidney Transplant Recipients Switched from Cyclosporine or Tacrolimus to Belatacept: Results from the Long-Term Extension of a Phase II Study
J. Grinyó
Barcelona, Spain

Donor Sub-type Analysis of Three-year Outcomes from a Phase III Study of Belatacept in Recipients of Extended Criteria Donor Kidneys (BENEFIT-EXT Trial)
F. Mühlbacher
Vienna, Austria

Renal Function in Patients Treated with Belatacept- or Cyclosporine-based Regimens at Year 3 in the BENEFIT and BENEFIT-EXT Studies
A. Durrbach
Paris, France

Likelihood of Improving or Sustaining Renal Function over Three Years with Belatacept or CsA: Insights from the BENEFIT Study
J. Grinyó
Barcelona, Spain

A Comparison of the Peripheral Blood mRNA Transcriptional Profile of Belatacept- and Cyclosporine-treated Renal Transplant Patients
B. Ganguly
Princeton, NJ

Rationale for Belatacept Less Intensive Regimen in Renal Transplant Recipients
J. Shen
Princeton, NJ

Predictable Pharmacokinetics, Pharmacodynamics, and Exposure-response of Belatacept and the Need of Therapeutic Drug Monitoring
J. Shen
Princeton, NJ

Belatacept 6-Month Intravenous Toxicity Study in Monkeys
H. Haggerty
New Brunswick, NJ

Association between early changes in chronic kidney disease stage following kidney transplantation and graft survival
W. Irish
Cincinnati, OH

New onset diabetes after transplant: Data from the international PORT study
B. Kasiske
Minneapolis, MN

About NULOJIX® (belatacept)

NULOJIX is the first selective T-cell costimulation blocker approved by the U.S. Food and Drug Administration indicated for the prophylaxis of organ rejection in adult patients receiving a kidney transplant, in combination with basiliximab induction, mycophenolate mofetil (MMF), and corticosteroids. NULOJIX should only be used in patients who are EBV seropositive. Use of NULOJIX for prophylaxis of organ rejection in transplanted organs other than kidney has not been established. In vitro, belatacept inhibits T lymphocyte proliferation and the production of the cytokines interleukin-2, interferon-g, interleukin-4, and TNF-a. Activated T cells are the predominant mediators of immunologic rejection.

IMPORTANT SAFETY INFORMATION

Post-Transplant Lymphoproliferative Disorder (PTLD)
• NULOJIX® (belatacept) patients are at increased risk for developing PTLD, predominantly involving the central nervous system (CNS).

• Recipients without immunity to Epstein-Barr virus (EBV seronegative) are at particularly increased risk; therefore, NULOJIX® (belatacept) is contraindicated in transplant recipients who are EBV seronegative or unknown serostatus.

• Monitor for new or worsening neurological, cognitive, or behavioral signs and symptoms.

• As the total burden of immunosuppression is a risk factor for PTLD, higher than recommended doses or more frequent dosing of NULOJIX or concomitant immunosuppressive agents are not recommended.

• Other known risk factors for PTLD include cytomegalovirus (CMV) infection and T-cell-depleting therapy.
  - CMV prophylaxis is recommended for at least 3 months after transplantation.
  - Use T-cell-depleting therapy to treat acute rejection cautiously.

• Patients who are EBV seropositive and CMV seronegative may be at increased risk of PTLD
  - Since CMV seronegative patients are at increased risk for CMV disease (a known risk factor for PTLD), the clinical significance of CMV serology for PTLD remains to be determined; however, these findings should be considered when prescribing NULOJIX.

Management of Immunosuppression

• Only physicians experienced in immunosuppressive therapy and management of kidney transplant patients should prescribe NULOJIX.
  - Patients should be managed in facilities with adequate laboratory and supportive medical resources.
  - The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient.

Progressive Multifocal Leukoencephalopathy (PML)

• NULOJIX patients are at increased risk for PML, often a rapidly progressive and fatal opportunistic infection
  - In clinical trials, two cases were reported in patients receiving NULOJIX at higher cumulative doses and more frequently than the recommended regimen, along with MMF and corticosteroids; one occurred in a kidney transplant recipient and one occurred in a liver transplant recipient

• As PML has been associated with high levels of immunosuppression, higher than recommended doses or more frequent dosing of NULOJIX® (belatacept) and concomitant immunosuppressive agents, including MMF, are not recommended.

• Monitor for new or worsening neurological, cognitive, or behavioral signs and symptoms
  - PML is usually diagnosed by brain imaging, cerebrospinal fluid testing for JC viral DNA by polymerase chain reaction, and/or brain biopsy.
  - Consultation with a specialist should be considered.
  - If PML is diagnosed, consider reduction or withdrawal of immunosuppression, weighing risk to the graft.

Other Malignancies and Serious Infections

• Increased susceptibility to infection and possible development of malignancies may result from immunosuppression.

• Patients should avoid prolonged exposure to ultraviolet light and sunlight.

• Patients receiving immunosuppressants, including NULOJIX, are at increased risk for bacterial, viral, fungal, and protozoal infections, including opportunistic infections and tuberculosis. Some infections were fatal.
  - Polyoma virus-associated nephropathy can lead to deteriorating renal function and graft loss; consider reduction in immunosuppression, weighing risk to the graft.
  - Tuberculosis was more frequently observed in patients receiving NULOJIX. Evaluate for tuberculosis and initiate treatment for latent infection prior to NULOJIX use.
  - CMV and Pneumocystis jiroveci prophylaxis is recommended after transplantation.

Liver Transplant: use in liver transplant patients is not recommended due to increased risk of graft loss and death in a clinical trial with more frequent administration of NULOJIX than studied in kidney transplant, along with MMF and corticosteroids.

Immunizations: avoid use of live vaccines during NULOJIX treatment.

Pregnancy Category C: based on animal data, NULOJIX may cause fetal harm. NULOJIX should not be used in pregnancy unless potential benefit to the mother outweighs potential risk to the fetus. To monitor maternal-fetal outcomes of pregnant women who have received NULOJIX® (belatacept), or whose partners have received NULOJIX, healthcare providers are strongly encouraged to register pregnant patients in the National Transplant Pregnancy Registry (NTPR) by calling 1-877-955-6877.

Nursing Mothers: discontinue NULOJIX or nursing, considering importance of NULOJIX to the mother.

Most Common Adverse Reactions (≥20%): anemia (45%), diarrhea (39%), urinary tract infection (37%), peripheral edema (34%), constipation (33%), hypertension (32%), pyrexia (28%), graft dysfunction (25%), cough (24%), nausea (24%),
vomiting (22%), headache (21%), hypokalemia (21%), hyperkalemia (20%), and leukopenia (20%).

Please see accompanying Full Prescribing Information, including Boxed WARNINGS, or visit www.NULOJIX.com or www.bms.com.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company committed to discovering, developing and delivering innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

Language:
English

Contact:

Bristol-Myers Squibb Company
Media:
Ken Dominski, +1 609-252-5251
ken.dominski@bms.com
or
Celine Van Dooselaere, +33 1-58-83-60-27
celine.vandooselaere@bms.com
or
Investors:
John Elicker, +1 609-252-4611
john.elicker@bms.com

Ticker Slug:
Ticker: BMY
Exchange: NYSE