

22.11.2006 - 15:35 Uhr

## **SPRYCEL(TM) (Dasatinib) Approved in Europe - the First Significant Advance for Treatment-Resistant CML and Ph+ ALL Leukaemia Patients in Five Years**

*Paris, November 22 (ots/PRNewswire) -*

- New Hope for CML and Ph+ ALL Patients who Face Resistance or Intolerance to Current Therapies

For Non-US Journalists Only

Today, the European Commission approved SPRYCEL(TM) (dasatinib, formerly known as BMS-354825) for the treatment of adults with chronic, accelerated or blast phase chronic myeloid leukaemia (CML) with resistance or intolerance to prior therapy, including imatinib mesylate. SPRYCEL is also indicated for the treatment of adults with Philadelphia chromosome positive (Ph+) acute lymphoblastic leukaemia (ALL) and lymphoid blast CML with resistance or intolerance to prior therapy.

SPRYCEL, which has been granted orphan drug status, received rapid approval from regulatory authorities in Europe. In June 2006, the U.S. Food and Drug Administration granted accelerated approval to SPRYCEL for CML with resistance, or intolerance, to prior therapies and approval for Ph+ ALL with resistance or intolerance to prior therapies.

For patients with CML or Ph+ ALL, the development of resistance or intolerance to standard treatment can be a devastating event. The potential for drug resistance to develop may increase with length of prior treatment and the stage of disease. Emerging evidence from a single European centre study indicates that resistance to imatinib mesylate may occur in approximately 25% of chronic phase CML patients, 41% of accelerated phase patients and 92% of blast crisis patients.(1) Until today, limited therapeutic options have been available to these patients.

"SPRYCEL was discovered and has been developed by Bristol-Myers Squibb scientists to help CML and Ph+ ALL patients who face a serious problem of resistance or intolerance to the current standard treatment," said Beatrice Cazala, president, Europe, Middle East and Africa for Bristol-Myers Squibb. "With the approval of SPRYCEL in Europe, these patients now have an effective therapeutic option that can overcome treatment resistance and intolerance in certain cases."

Resistance to therapy is thought to involve the following mechanisms:(2)

- mutations of Bcr-Abl, the key protein responsible for CML and Ph+ ALL
- overexpression of Bcr-Abl
- other proteins involved in cancer pathways, such as the Src pathway,

which is thought to play a role in CML and Ph+ ALL as well as other cancers.

Mutations can change the shape of the Bcr-Abl protein. When this happens, imatinib mesylate, the current standard treatment, may be unable to block its activity. SPRYCEL is an oral, multi-targeted therapy that can inhibit the action of Bcr-Abl in the presence of all but one known mutation.(3,4)

Professor François Guilhot, Professor of Haematology, Director of the Clinical Research Centre, University Hospital La Miletrie, Poitiers, France; President of the French Chronic Myelogenous Leukemia Group commented: "Initial clinical trials demonstrate that SPRYCEL can affect leukaemic cell growth enabling many adults with CML or Ph+ ALL to control their disease over a sustained period of time. In a Phase II study, SPRYCEL demonstrated significant haematological and cytogenetic efficacy in imatinib mesylate-resistant and -intolerant CML patients in chronic phase; moreover, in the majority of patients with chronic phase CML who had become resistant to standard therapy, responses were durable. It is worth noting that as early as in the Phase I study, haematologic and cytogenetic responses were observed in all phases of CML and in Ph+ ALL in the first 84 patients treated and followed for up to 19 months. Responses were durable across all phases of CML and Ph+ ALL."

The European Medicines Agency reviewed the efficacy and safety of SPRYCEL based on the analysis of five Phase II multi-centre studies in patients with resistance or intolerance to imatinib mesylate in all phases of CML or Ph+ ALL.(2) The studies were conducted on five continents (33 countries) and SPRYCEL was shown to have a predictable and manageable side-effect profile. In the 911 patients receiving SPRYCEL in clinical trials, the most common side effects were fluid retention (including pleural effusion and peripheral oedema), gastrointestinal (diarrhoea, nausea and vomiting), skin rash, headache, haemorrhage, fatigue, and dyspnoea (difficulty in breathing).

Myelosuppression (a reduction in blood-cell production by the bone marrow) was reported in all studies and was generally reversible. The frequency was higher in patients with advanced CML or Ph+ ALL than in chronic phase CML.(2)

Full SPRYCEL Product Information and the European Public Assessment Report (EPAR) will be available at [www.emea.europa.eu](http://www.emea.europa.eu)

SPRYCEL is available in Austria, Germany, France, Finland, Sweden and the United Kingdom. Availability in other European countries is subject to individual country regulations, including pricing and reimbursement laws.

#### About Bristol-Myers Squibb

Bristol-Myers Squibb is dedicated to the discovery, development and exhaustive exploration of innovative cancer-fighting therapies that extend and enhance the lives of patients living with cancer. More than 40 years ago, Bristol-Myers Squibb built a unified vision for the future of cancer treatment. With expertise, dedication and resolve, that vision led to the development of a diverse global portfolio of anti-cancer therapies that are an important cornerstone of care today. Hundreds of scientists at Bristol-Myers Squibb's Pharmaceutical Research Institute are studying ways to improve current cancer treatments and identify better, more effective medicines for the future.

Bristol-Myers Squibb is a global pharmaceutical and related health care products company whose mission is to extend and enhance human life.

#### REFERENCES

1. Lahaye T, Riehm B, Berger U et al. Cancer 2005;103:1659-69.
2. SPRYCEL(TM) Summary of Product Characteristics.

3. Talpaz M, Shah NP, Kantarjian H et al. N Engl J Med  
2006;354:2531-41

4. O'Hare T, Walters DK, Stoffregen EP et al. Cancer Res  
2005;65:4500-5

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