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BresaGen develops production process for G-CSF

Adelaide-based biotech Company BresaGen, announced today that it has successfully developed a process for the production of recombinant methionyl human granulocyte colony stimulating factor (G-CSF). G-CSF is the active substance in filgrastim, used in the treatment of neutropenia.

In May 2005, the Company announced its intention to develop G-CSF as an active pharmaceutical ingredient (API) for sale to pharmaceutical companies targeting the registration and marketing of biosimilar products. A 'biosimilar' (or biogeneric) is defined by a rigorous set of quality criteria as being similar to a biological medicine already authorized for use. Reductions in clinical requirements for biosimilar products have the potential to significantly reduce the cost of finished products compared to those of the innovator product. Development of BresaGen's G-CSF product commenced in September 2005, and has resulted in a viable commercial process, now in the process of being scaled-up for production in compliance with GMP for use in clinical trials.

The recent registration of two biosimilar human growth hormone (hGH) products in Europe has provided momentum to this area. This activity was boosted by the recent registration in the US of a biosimilar hGH product as well. Biosimilars could quickly address a \$10 billion market in which many treatments cost upwards of \$10,000 per patient per year.

The Company is actively seeking development and distribution partners for its G-CSF product for various geographic territories. Earlier this year, it successfully concluded a distribution agreement for India, and is in active negotiation for other territories.

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About BresaGen Limited (ASX:BGN)

BresaGen is an Australian biotechnology Company focussed on cost-effective production of proteins and peptides in bacteria. The Company is located in Adelaide, South Australia and specialises in process development and supply of clinical trial material for third parties through its protEcol[™] Services business unit. In addition, the Company supplies protein-based active pharmaceutical ingredients (API's) to pharmaceutical and biotechnology companies.

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