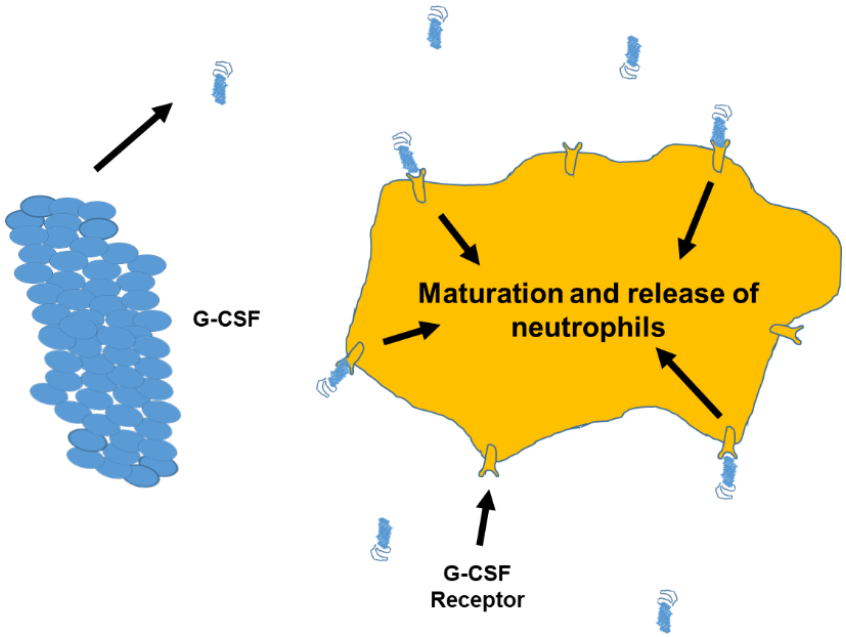
G-CSF – Fact Sheet

Molecule

Filgrastim (granulocyte colony stimulating factor, G-CSF, Neupogen®) consists of 175 amino acid residues (18.8 kDa) with two disulfide bridges and is manufactured in E. coli.

Mode of Action

Filgrastim binds to the G-CSF receptor, stimulates the proliferation of progenitor cells and their maturation into neutrophils (white blood cells). Filgrastim also stimulates the release of neutrophils from bone marrow and increases their phagocytic activity. By stimulation of the production of more neutrophils, filgrastim treatment can thus be used to fight infection in patients undergoing chemotherapy for cancer treatment.



Indication

Neupogen® is approved for five indications in the following patient populations:

Chemotherapy -induced Febrile Neutropenia, Acute Myeloid Leukemia, Cancer Patients Receiving Bone Marrow Transplant, Peripheral Blood Progenitor Cell Collection and Engraftment, and Severe Chronic Neutropenia.

Patent Situation

Patents on Neupogen® expired in the US in December 2013 and in Europe in 2006.

Market and Competitive Field

The originator product, Amgen's Neupogen® was approved by FDA in 1991 for the first time. Neupogen® had worldwide sales of 1.2 billion Euro in 2013 before the approval of the first filgrastim biosimilars. In 2017 revenues fell to 477 million Euro. Zarzio® (Novartis) is the number one filgrastim biosimilar globally. Among others, marketed biosimilars are Accofil® (Accord / Intas), Grastofil® (Apotex), and Nivestim® (Pfizer).

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	G-CSF
	e.g. Neupogen®, Nivestim® Grastofil®, Accofil® Zarxio® / Zarzio®
Clone selection/ comparability	
Affinity to recombinant target – kinetics (Biacore)	G-CSF-R
Cell-based bioassay	
(Pre)clinical application	
Pharmacokinetics (ECL or ELISA)	
Immunogenicity (Biacore/ ELISA/ bioassay)	
Batch release EU	Full portfolio according to product specification

Vela Portfolio

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