

002019

2020-044

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III

		Primary end point		secondary end
point			Neulasta®	F-627
	F-627		F-627	
	F-627	III		
F-627	III			
		F-627 05		
F-627			F	F-627
	F-627			
	F-627		Di-Kine™	
			G-CSF	Fc
	CHO	rhG-CSF	F-627	
Ä				

F-627 III
 ICH-GCP 2017
 10 6 FDA F-627 05
 SPA FDA
 III 05 04
 5 41
 2018 4 2020 3 05
 393 1:1 F-627
 Neulasta® 21 05
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 4
 FN FN
 F-627 05
<http://clinicaltrials.gov> [NCT03252431](https://clinicaltrials.gov/ct2/show/study/NCT03252431)
 05 F-627 4
 Neulasta®
 95% -0.1 0.1 0.6 F-627
 05 4
 FN
 FN
 Neulasta® F-627 05
 BLA
 FDA
 BLA
 BLA
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II III F-627 I
 III G-CSF I II

FDA 05

BLA
 BLA BLA

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IMS 2019 G-CSF 45
 88% Neulasta 73%
 Neulasta 4
 2018 7 Fulphila 2019 1 Udenyca 2020
 1 Ziextenzo 2020 6 Nyvepria 2019
 Fulphila Udenyca 7.09
 15.56% 1
 2019 G-CSF 5.11 3
 2012 3 2015 12 2018 7
 2017 7700 2019 3.10
 2017 26% 2019 61%
 G-CSF

1 F-627 05
 F-627 III

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