
Chair's Introduction

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ATMP's Under Development in the EU

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Clinical Development of Advanced Therapy Medicinal Products in Europe: Evidence That Regulators Must Be Proactive

Romaldas Maciulaitis^{1,2}, Lucia D'Apote³, Andrew Buchanan³,
Laura Pioppo^{3,4} and Christian K Schneider^{1,5,6}

doi:10.1038/mt.2012.13

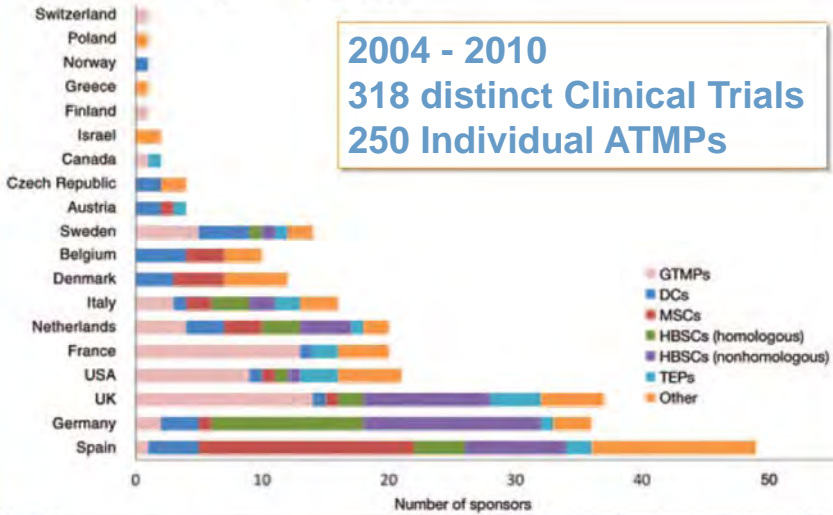
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EU: ATMP Clinical Trial Activity

Number of ATMPs by country and type



EMA: Medicines under evaluation

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Medicines under evaluation

This page lists information on applications for centralised marketing authorisations for **human medicines** that are under evaluation by the Committee for Medicinal Products for Human Use (CHMP).

Document(s)	Language	Status	First published	Last updated	Effective Date
Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use: May 2012	(English only)		14/05/2012		
Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use: April 2012	(English only)		11/04/2012	20/04/2012	
Applications for new human medicines under evaluation by the Committee for Medicinal Products for Human Use: March 2012	(English only)		01/03/2012	02/03/2012	

ATMP's Under Evaluation at EMA

14 May 2012

International non-proprietary name (salt, ester, derivative, etc.) / Common Name

Therapeutic area¹

Probably Anika Therapeutics, Hyalograft C.

Autologous cultured chondrocytes

Other medicines for disorders of the musculo-skeletal system

Autologous oral mucosal epithelial cells

Ophthalmologicals

Autologous peripheral blood mononuclear cells activated with PAP-GM-CSF

Immunostimulants

Cultured autologous chondrocytes on hyaluronan based scaffold

Other medicines for disorders of the musculo-skeletal system

Probably Genzyme's, MACI.

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CellSeed

June 2011

Bloomberg

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Bridge Report on CellSeed Issued: 1H FY12/11 Sales and Operating Losses in Line with Expectations, FY12/11 Estimates

In the first half of FY12/11, CellSeed recorded 88.5% year-over-year growth in sales to JPY43 million. While no sales were recorded in the cell sheet regenerative medicine business segment, the approval application for the commercial launch of corneal regeneration epithelial cell sheet applications was accepted by the European Medicines Agency in June and represents a positive step towards realizing revenues. At the same time CellSeed incurred losses at the operating and recurring levels of JPY639 and JPY584 million, which compares with JPY549 and JPY246 million in the same term of the previous

Business Wire

TOKYO -- September 14, 2011

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Dendreon

January 2012

PRESS RELEASE

Feb. 27, 2012, 8:30 a.m. EST

Dendreon Reports Fourth Quarter and 2011 Year End Financial Results

– Conference Call to be Hosted February 27, 2012 at 9:00 a.m. ET/6:00 a.m. PT –



SEATTLE, Feb. 27, 2012 (BUSINESS WIRE) – February 27, 2012–Dendreon Corporation **DNDN -4.97%** today reported results for the year and quarter ended December 31, 2011. Product revenue for the year ended December 31, 2011 was \$213.5 million compared to \$48 million for the year ended December 31, 2010. Product revenue for the fourth quarter of 2011 was \$77 million compared to \$25 million for the quarter ended December 31, 2010.

– Filed the marketing authorization application (MAA) for PROVENGE with the European Medicines Agency, which was validated in January.



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How do we justify the cost?

UK's NICE does U-turn, recommending Zytiga as Janssen cuts price

Article | 16 May 2012

Print This Share This

UK drugs watch dog the National Institute for Health and Clinical Excellence (NICE) has reversed an earlier negative decision (The Pharma Letter February 2), issuing new draft guidance recommending the National Health Service use of Zytiga (abiraterone), from Johnson & Johnson's (NYSE: JNJ) Janssen unit, in combination with prednisone or prednisolone for the treatment of castration-resistant metastatic prostate cancer that has progressed after one docetaxel-containing therapy.



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