Chair's Introduction

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ATMP's Under Development in the EU

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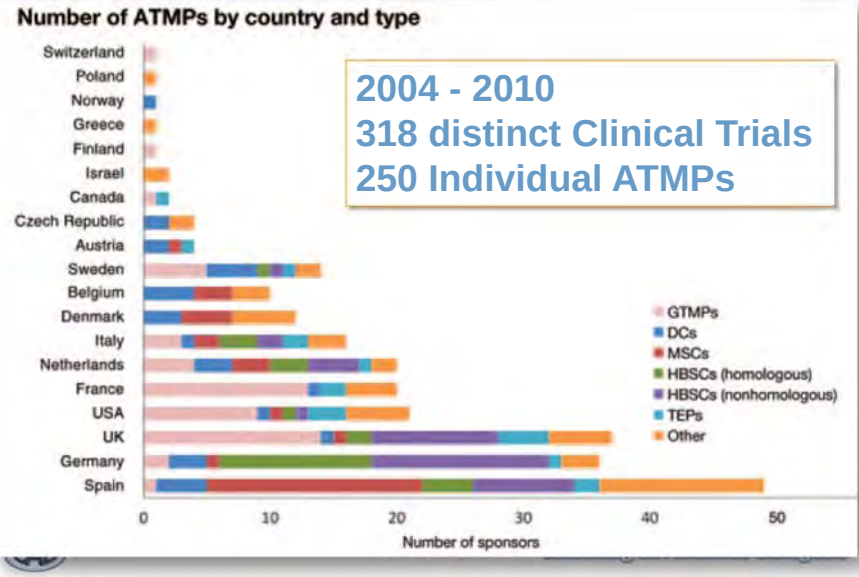
Clinical Development of Advanced Therapy Medicinal Products in Europe: Evidence That Regulators Must Be Proactive

Romaldas Maciulaitis[1,2], Lucia D'Apote[3], Andrew Buchanan[3], Laura Pioppo[3,4] and Christian K Schneider[1,5,6]

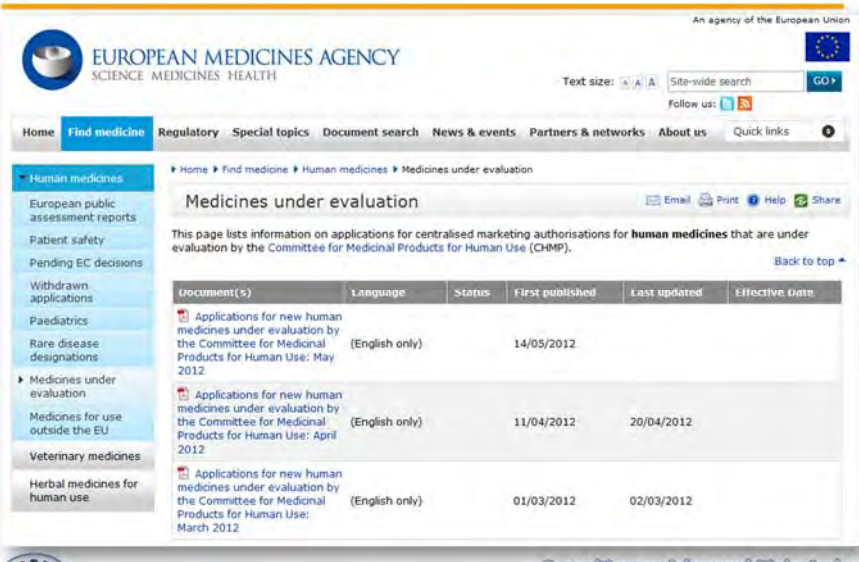
doi:10.1038/mt.2012.13

EU: ATMP Clinical Trial Activity



2004 - 2010
318 distinct Clinical Trials
250 Individual ATMPs

EMA: Medicines under evaluation



ATMP's Under Evaluation at EMA

14 May 2012

International non-proprietary name (salt, ester, derivative, etc.) / Common Name	Therapeutic area[1]
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 Anika Therapeutics, Hyalograft C.

Probably Genzyme's, MACI.

CellSeed

June 2011

Bloomberg Our Company | Professional | Anywhere |

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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,

Business Wire

TOKYO -- September 14, 2011

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 –

BusinessWire
A Berkshire Hathaway Company

Dendreon

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.

CAB Consulting on Advanced Biologicals

How do we justify the cost?

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

Article | 16 May 2012

Print This ShareThis

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.

CAB Consulting on Advanced Biologicals