

Continuous CI monitoring in multiple sclerosis

CLIENT

**Leading Pharma
Company**

THERAPY AREA

Neurology



BUSINESS IMPACT

- Helped shape promotional strategies in line with shift in market trend from platform agents to high-efficacy therapies (orals and IVs)
- Analysed the impact of Ocrevus launch on oral agents and high-efficacy MAbs



PROJECT OBJECTIVES

- Helped shape promotional strategies in line with shift in market trend from platform agents to high-efficacy therapies (orals and IVs)Analysed the impact of Ocrevus launch on oral agents and high-efficacy MAb
- To derive actionable insights by analysing information gathered from multiple data sources



SCOPE

- Geography: Global
- Disease segment: Relapsing and progressive forms of multiple sclerosis
- Treatment landscape:
 - Disease-modifying agents to control relapses and disease progression
 - Platform agents and high-efficacy therapies

SOLUTION APPROACH

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- Define KITs/KIQs based on clinical, scientific and commercial relevance
 - Develop a comprehensive secondary research methodology
 - Synthesis and analysis of data from multiple sources, e.g., clinical trial registries, client data, company websites, primary market research, conferences, newswires, syndicated data, social media data, primary and secondary data

KEY DELIVERABLES

- News alerts: High-impact events reported within 3 hours with a brief analysis
- Weekly newsletters: Events of the week with commentary/takeaways
- Monthly/quarterly reports: Key events of the month/quarter and their impact; in-depth product and competitor perspective analysis integrating relevant primary intel/conference CI

SAMPLE DELIVERABLES

SNAPSHOT OF Q1 2020

Regulatory

- Zeposia (ozanimod) approved in the US and received positive CHMP opinion in the EU in Mar'20
- Mayzent approved in the EU in Jan'20
- Ofatumumab sBLA and MAA accepted in the US and EU, respectively in Feb'20
- Ponesimod NDA and MAA submitted in the US and EU in Mar'20
- Avonex & Plegridy: US labels updated to comply with Pregnancy and Lactation Labeling Rule (PLLR). Pregnancy risk category C is now removed from section 8.1

Patent

- Biogen won a favorable ruling for Tecfidera's '514 patent against Mylan
- Banner received favorable ruling against Biogen for Tecfidera's '001 patent infringement challenge

Clinical

- Positive top-line results from SAR442168's Phase2b dose-finding study in RMS were announced
- Positive top-line results from masitinib's Phase 2/3 study in progressive forms of MS (PPMS and non-active SPMS) were announced
- MD1003 failed to meet primary and secondary endpoints in Phase 3 SPI2 study

Market Access

- Tecfidera is now available as a 1st-line treatment for RRMS patients under the Unified Health System (SUS), Brazil
- Interministerial Commission for Drug Prices (CIPM), Spain included Gilenya's pediatric RMS indication for public funding of the National Health System (SNS)

Q4'19 earnings

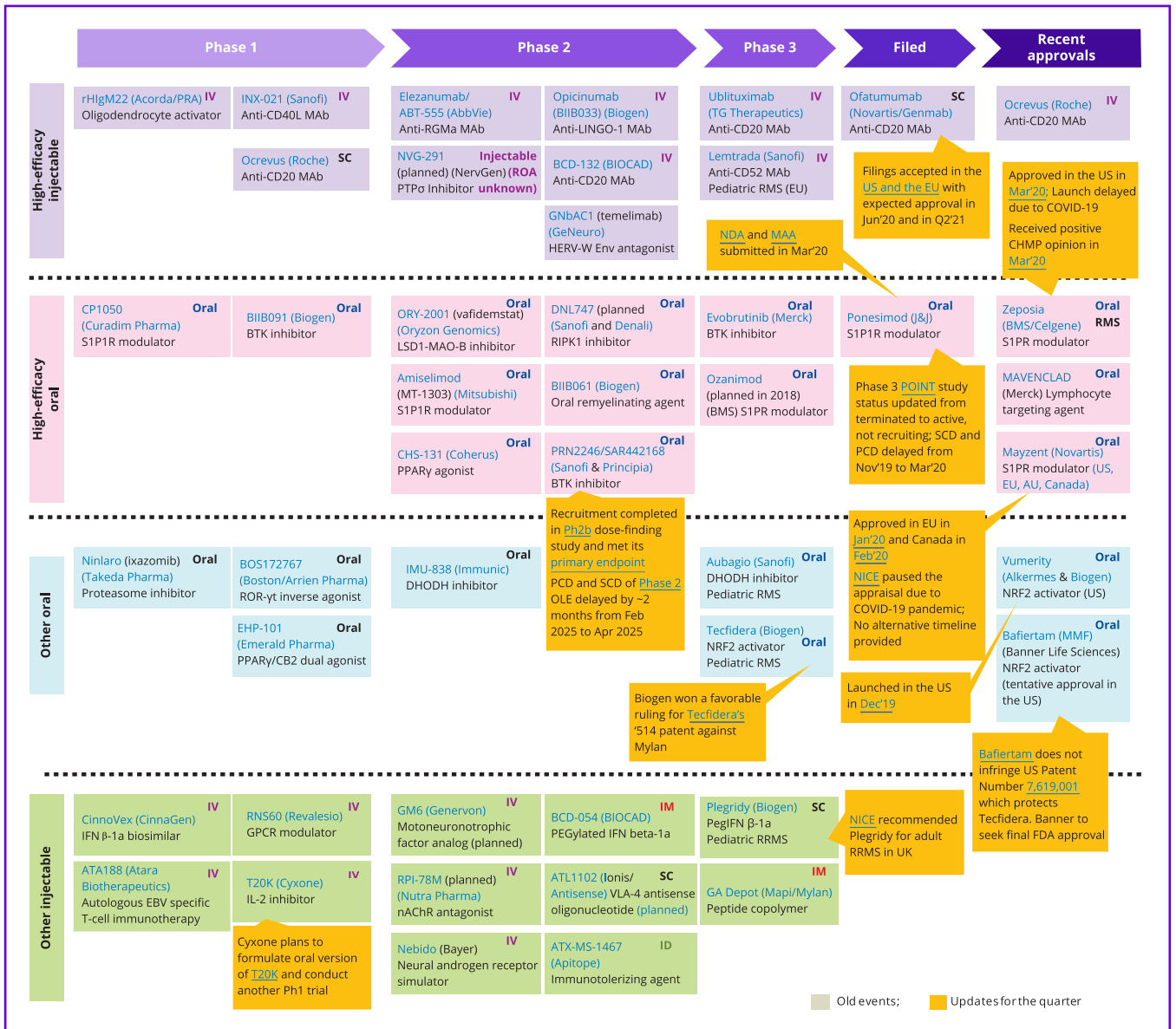
Drug/Company	Global Sales (€)*	% change
Ocrevus/ Roche	981 M	55% increase vs Q4'18
Gilenya/ Novartis	750 M	3% decrease vs Q4'18 due to competitive pressure
Mayzent/ Novartis	16 M	
Tecfidera/ Biogen	1,085 M	5% increase vs Q4'18
Tysabri/ Biogen	442 M	2% increase vs Q4'18
Avonex + Plegridy/ Biogen	482 M	14% decrease vs Q4'18 due to continued shift from injectable platforms to oral or high-efficacy therapies
Vumerity/ Biogen & Alkermes	5 M	
Aubagio/ Sanofi	482 M	5.4% increase vs Q4'18
Lemtrada/ Sanofi	58 M	41.7% decrease vs Q4'18 due to increased global competition and the update to the EU label
Copaxone/ Teva	362 M	21.65%* decrease vs Q4'18 due to generic competition in the US
Betaferon/ Betaseron/ Bayer	125 M	11.8% decrease due to strong competition in the US
Glatopa/ Novartis & Momenta	7 M	27% decrease vs Q4'18 due to lower sales driven by competition

Key upcoming events

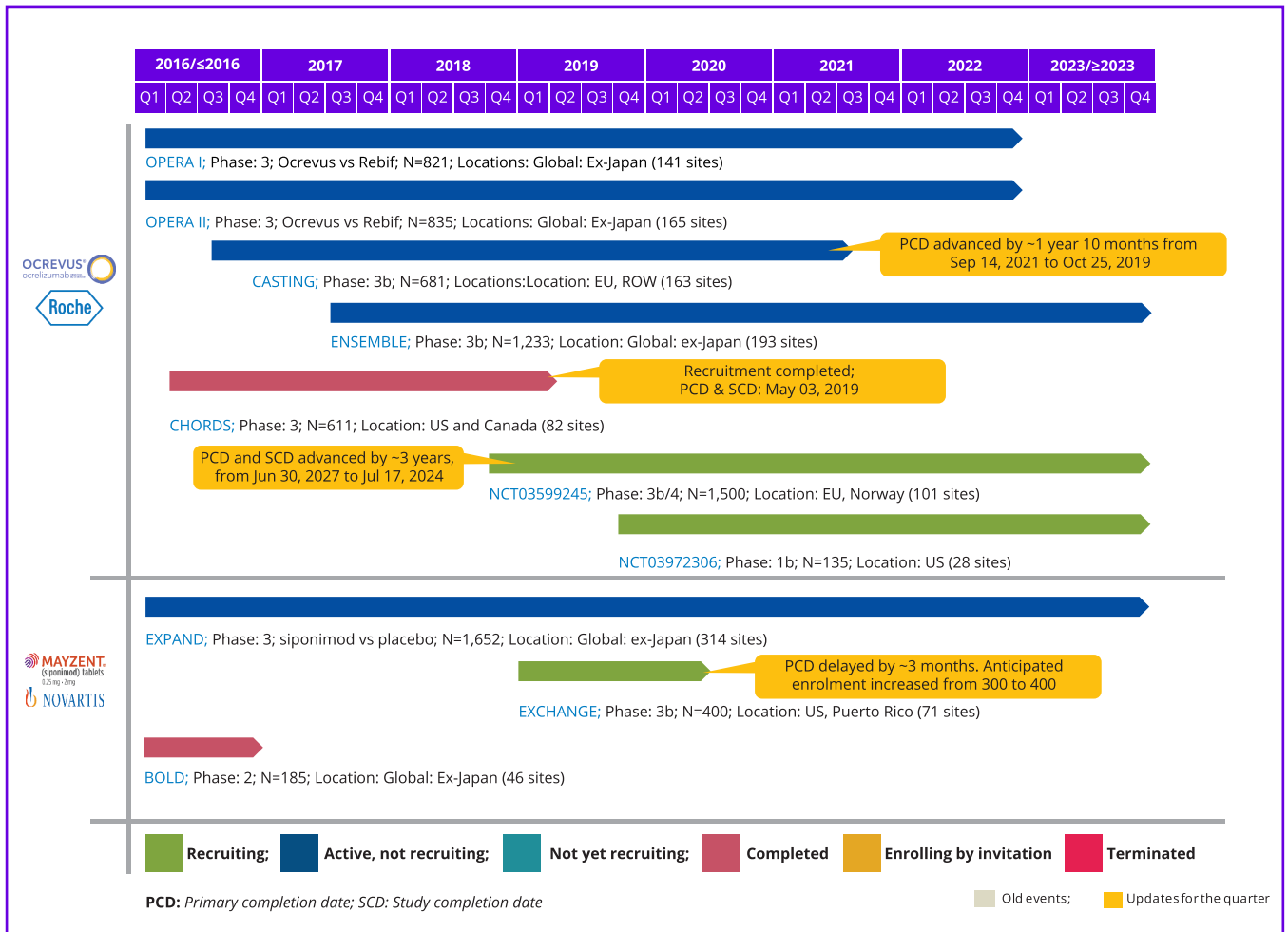
- Zeposia EU approval: End-May/Early-Jun'20
- Ofatumumab's US approval: Jun'20
- SAR442168's planned Phase 3 studies: Mid-2020
- Bafiertam expected US approval: Jun'20

* Reported values were converted into €

PIPELINE SNAPSHOT - RMS



KEY CLINICAL TRIALS IN RMS



ABOUT US

C5i is a pure-play AI & Analytics provider that combines the power of human perspective with AI technology to deliver trustworthy intelligence. The company drives value through a comprehensive solution set, integrating multifunctional teams that have technical and business domain expertise with a robust suite of products, solutions, and accelerators tailored for various horizontal and industry-specific use cases. At the core, C5i's focus is to deliver business impact at speed and scale by driving adoption of AI-assisted decision-making.

C5i caters to some of the world's largest enterprises, including many Fortune 500 companies. The company's clients span Technology, Media, and Telecom (TMT), Pharma & Lifesciences, CPG, Retail, Banking, and other sectors. C5i has been recognized by leading industry analysts like Gartner and Forrester for its Analytics and AI capabilities and proprietary AI-based platforms.



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