



Congress

Intelligence gathering all in one place

Usually takes place over 3-5 days



Case Study: Neuroimmunology Congress Coverage

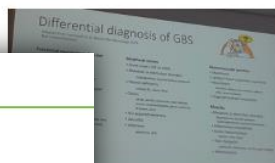
Congress Planner

2022 ICNMD Conference						
Important Links:	ICNMD 2022 Congress Website	ICNMD 2022 Congress Program				
Tuesday, July 5th Event Time (Local)	Event Title	Submissions	Event Speakers and Affiliations	Priority	Assigned Analyst	Note
9:00 AM - 12:00 PM	TC02: Diagnosis and Treatment of GBS, CIDP and Autoimmune Nodopathies "Fluked Session"	1. 2022 EANPG GBS Guideline 2. 2021 EANPG CIDP Guideline 3. Autoimmune Nodopathies 4. Biomarkers and Outcome Measures in Immune-mediated Neuropathies	1. Dr. Rob Heiden, Neurologist, King's College Hospital 2. M. PhD, Professor Peter Van den Bergh, Consultant Neuroimmunology, Ghent University Ghent, Ghent University Ghent, Ghent University Ghent 3. Dr. Luis Antonio Quaresima, Neurologist, LFB BIOMEDICAMENTS 4. Dr. JEFFREY ALLLEN, Associate Professor, University of Minnesota	High	Analyst 1	
9:00 AM - 12:00 PM	TC03: Towards Targeted Treatments in Myasthenia Gravis: Update on Pathogenesis Mechanism and New Drugs "Fluked Session"	1. Towards Targeted Therapies in Myasthenia Gravis: Pathogenic Mechanism Focused on Treatments 2. Complement Inhibitor Therapy for Myasthenia Gravis 3. The role of FcRn Antagonists in MG Treatment 4. Peripheral nervous system complications of severe cholinesterase inhibitors	1. Dr. Pooja Narasimhan, Associate Professor of Neurology (PMS), Vice-Chair, Clinical Operations (SNOAC) 2. Dr. Sarah Mappin, Associate Professor, Stanford University School of Medicine 3. Professor Nils-Erik Gilhus, Professor, University of Bergen 4. Prof. Jan De Becker, Professor of Neurology	High	Analyst 2	
Wednesday, July 6th Event Time (Local)	Event Title	No Sessions Detected				
Thursday, July 7th Event Time (Local)	Event Title					

Commercial Interview

Booth Primary Intelligence Gathering

- *Rozy* study
- Phase 3 – results promising (unpublished). Hopefully published at the end of 2023.
- Showed significant clinical effect vs placebo
- Reduced IgG
- Dosing: 7mg/kg and 10mg/kg
 - o 10mg showed significantly higher serious adverse events – 7 and 10mg/kg both show similar levels of clinical improvement.
 - o 7mg showed serious adverse events aligned with placebo
 - o Dosing: once a week for 6 weeks, then in an 8-week observation phase, if a patient has relapse, then they are assigned saviour therapy either further cycle of *Rozy* or PE/IVIg.
 - o Choice of 10mg/kg was due to CIDP phase 2 study. Phase 2 study has been cancelled due to lack of efficacy.
 - * This could be due to patient population
- Published later on this year, at MNDC conference?
- Use cases: eMG
- Not CIDP



What

Our client was unable to attend a congress and commissioned Dig Worldwide to attend and conduct primary intelligence for existing and emerging treatment paradigms for three therapy areas.

Daily summaries were provided to the client, as well as a mid- and post- congress call to share key insights.

Why

Our client required European coverage of the ICNMD Congress as they were unable to attend themselves.

A list of key intelligence questions formed part of a long-term monitoring project for the client and required on-the-ground primary intelligence engaging with KOLs and commercial sources.

Where

EU

How

A Dig analyst attended the ICNMD Congress in Brussels to attend high priority sessions; identify clinical and commercial KOLs through networking and research answers to a list of key intelligence questions.

TC02: Autoimmune Nodopathies

CIDP

- * 10% patients diagnosed with CIDP likely to have autoimmune nodopathies
- * Similar features: Aggressive onset; Motor; Don't respond well to IVIg/PE and corticosteroids, do respond to rituximab; Axonal damage; IgG4 isotype predominant
- * CNTN1 / CASPR1 complex on axon bind to NF-155 on myelin to keep it tethered. Antibodies that bind to these (mostly IgG4s) cause pathogenesis as the myelin becomes unstuck. Treatment of autoimmune nodopathies with rituximab usually provides long-lasting response (after 6-7 years, 80% don't need retreatment)
 - Different biomarkers related to different clinical features
 - Diagnose with cell-based assays – immunohistochemistry
 - Rituximab is good but not fast – significant drop in antibody titre by 3 months, 80% reduction by 6 months
 - Clinical improvement delayed, and PE is used until onset of rituximab's effect
 - Tiny patient population – diagnosed as CIDP and identified after long-term treatment failure
 - PE is used to wash out IgG4s before treatment with rituximab.
 - As pathogenesis involves IgG4s, analyst asked whether FcRns would be appropriate to replace PE.
- * FcRn in theory should work and presents a promising albeit expensive approach. The clinical trial currently studying CIDP patients with Argenx's efgartigimod recruits CIDP patients. As the autoimmune nodopathies present a very small subset of these patients, results will be diluted and may not show statistical significance. Also, FcRns are less selective to IgG4, and so the effect may be less pronounced





Case Study: Immunology Congress Coverage

Trial	Phase 2a	Phase 2b	Phase 2c
Study Design	N=95, triple blind, 1:1:1 randomization to 4 arms (150 mg, 300 mg, 900 mg, Placebo), QD dosing, 12 weeks	N=150, triple blind, 1:1:1 randomization to 3 arms (450 mg, 150 mg, placebo), BID dosing, 12 weeks	N=35, open label, one arm, 100 mg BID, 12 weeks
1st Outcome	Proportion of patients with clinical remission (Mayo)	Proportion of patients with clinical remission (Mayo)	Robarts Histopathologic Index (RHI) at week 12
2nd Outcome	N/A	Comparison between PN-943 high-dose and low-dose individually to placebo: endoscopic and histological improvement/remission, mucosal healing	<ul style="list-style-type: none"> TEAEs Modified mayo clinic score Cmax, Tmax, UAC during single and multiple doses
Inclusion Criteria	<ul style="list-style-type: none"> Age: 18-80 Mod-sev UC (Mayo score) Inadequate response to IM, TNF, or steroids Contraception 	<ul style="list-style-type: none"> Age: 18-75 Mod-sev UC (Mayo score) Inadequate response to 5-ASAs, steroids IM, or biologic excluding vedolizumab 	<ul style="list-style-type: none"> Age: 18-85 Mod-sev UC for > 3months UC extending at least 15 cm from the anal verge bio-naïve or had an inadequate response, loss of response, or intolerance to other UC drugs
Exclusion Criteria	<ul style="list-style-type: none"> CD (+/- fistula), ID Risk of colectomy Colonic dysplasia or polyps Infection/vaccination Immunodeficient 	<ul style="list-style-type: none"> CD, IC, microscopic colitis, ischemic colitis, radiation colitis Infection Prior treatment with vedolizumab, natalizumab, or any agent targeting the α4β7 or β1 integrin C.diff in stool Risk of pregnancy 	<ul style="list-style-type: none"> CD, IC, microscopic colitis, ischemic colitis, radiation colitis Primary non-responder to vedolizumab or other integrin inhibitors MORF-527 and/or a known hypersensitivity to drugs with a similar mechanism to MORF-527
Timeline	Terminated	PCD June 2022	PCD August 2023
Endpoints	12-week treatment. Final follow up at week 16.	12-week treatment. Final follow up at week 16.	12-week treatment
Data readout	Clinical, safety, pharmacokinetic (PK) and pharmacodynamic (PD) parameters	Expected April 2022	Expected 2H 2023
Results	DMC discontinued the trial due to fully-based outcome (contraversial)		
Clinical development	PIG-100 discontinued, PN-943 next gen molecule in progress		

Competitor Congress Activities Overview by Competitor – [REDACTED]

Competitor	Product	Current Status	Competitive Overview	UEGW Intel
[REDACTED]	[REDACTED]	Approved in UC EU (2021) P3 in CD	<ul style="list-style-type: none"> [REDACTED] preferential inhibitor [REDACTED] the agreement was amended in 2020 US rights remains unclear for [REDACTED] [REDACTED] still retain operational responsibility for the current trials in Crohn's disease Top line data expected in H1'23 for P3 program in CD 	[REDACTED]
[REDACTED]	[REDACTED]	Approved UC US and EU (2022) P3 in CD	<ul style="list-style-type: none"> [REDACTED] preferential inhibitor The FDA has included a boxed warning on serious infections and malignancy EMA is currently reviewing safety of JAK inhibitors for UC and will eventually amend marketing authorization [REDACTED] regulatory application to FDA and EMA for [REDACTED] 	[REDACTED]
[REDACTED]	[REDACTED]	Approved UC UC (not EU) (2018)	<ul style="list-style-type: none"> In 2019, the FDA approved new warnings about an increased risk of blood clots and deaths with the approved 10 mg BID dose [REDACTED] in 2020, the FDA [REDACTED] to minimize the [REDACTED] 	[REDACTED]

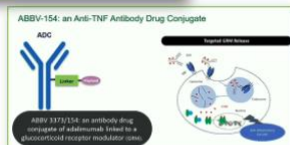
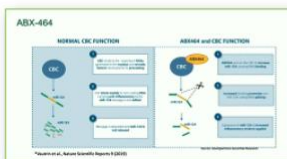
Session: What's New in 2022? IBD 9th October, Room A2 Upcoming Next Best Therapeutic Option for IBD by Dr. Tim Raine

Background:

- Discussed about IL23/19 mAbs, mechanism of action and the drugs in the pipeline in both UC and CD
- Provided an overview of the most advanced programs for JAK inhibitors pointing to impressive efficacy data for Upadacitinib
- Reviewed S1PR Ozanimod and Etrasimod
- Mentioned two promising new drugs in clinical development: ABBV-154 an anti-TNF ADC and ABX464 an oral sm.

Comment:

- [REDACTED]
- [REDACTED]
- [REDACTED]



What

Why

Where

How

Dig Worldwide attended an immunology congress in Europe on behalf of our client as part of an ongoing monitoring project.

Dig generated an in-depth report on the congress sessions, including key research data, and an analysis of how this impacts our client's relevant therapy area.

Our client owned early pipeline immunology assets and required a competitor landscape, running from actual to ten years out, focusing on new entrants that would compete with their asset.

Our client was also looking to understand the value of the assets as it prepared for an acquisition.

EU

Dig analysts attended the congress to conduct clinical and commercial primary intelligence focused on a list of key intelligence questions from KOLs. Each congress session was attended, and a report was delivered to the client.

