Mapi Pharma

2019

VALUE-ADDED HIGH BARRIER-TO-ENTRY PHARMACEUTICALS

Pipeline Key Products

505 (b) (2) Pathway Compound (Brand/Sales[1])	Indication	R&D / IP	Human PK	Phase II	Phase III and Registration
GA Depot (Copaxone®) 2018 $4.7bn	RRMS		Global Licensing		2021 Mylan
GA Depot (Copaxone®) 2018 $4.7bn	PPMS		Promising open study results		Phase III 2022
Pregabalin ER (Lyrica®) 2018 $5.0bn	Neuropathic Pain		Nhwa Regional Agreement		2020
Buspirone ER (BuSpar®) 2018 ~$80mm	Anti-psychotic (anxiety)		Nhwa Regional Agreement		

ANDA Pathway Compound (Brand/Sales[1])	Indication		Human PK	Registration	Marketing
Fingolimod (Gilenya®) 2018 $3.4bn	RRMS		Rafa IL/Adamed EU Marketing Agreement	**Approved IL May 2017**	Sales & Marketing IL/EU 2019-2020
gCopaxone (Copaxone®) 2018 $4.7bn	RRMS		**DMF 2020** ANDA 2021		Sales & Marketing IL/EU 2020-2021
Paliperidone (Once a month) (Deport injections) 2018 ~$2.9bn	Schizophrenia		Jingxin Regional Agreement **Phase II**		
Paliperidone (every 3 months) (Depot injection) 2018 $1.1bn	Schizophrenia		Chinese partner not disclosed **Phase II**		
Aripiprazole (Ability Maintena®) 2018 $1.1bn	Schizophrenia	Open for partnership			
GLP-1	Diabetes	Jingxin Regional Agreement			
Exenatide Depot	Diabetes	Open for partnership			

1. Cortellis Clarivate Analytics May 2019

GA Depot - $2-4 Billion Market Opportunity

Developing GA Depot as a premium drug to Copaxone® for MS patients with improved compliance, convenience and clinical outcome

PLGA microspheres
~10 micron GA-loaded

On-going Phase II (5 Years),
development under 505(b)(2)

Improved: Quality of Life, safety
by fewer AEs and tolerability and efficacy

Strong U.S. patent protection until 2030; three new patent applications under process to extend to 2037

Compliance maximized to ~100%, injection by nurse at patient's home or clinic

Phase 3 RRMS,
IND, single pivotal Phase III synopsis approved by FDA

GA Depot 40mg IM, once Every 4 weeks Patients and neurologists prefer a once-monthly injection

Good efficacy Excellent NEDA
of 84.6% observed in Phase II

Phase 2 PPMS on-going, all patients show stable EDSS or improved EDSS

Dr. Carlo Tornatore | New York, February 13, 2018 https://www.youtube.com/watch?v=5_UuFQrm2Nc

GA Depot Phase II RRMS 2 Year Efficacy

81.8% of Patients

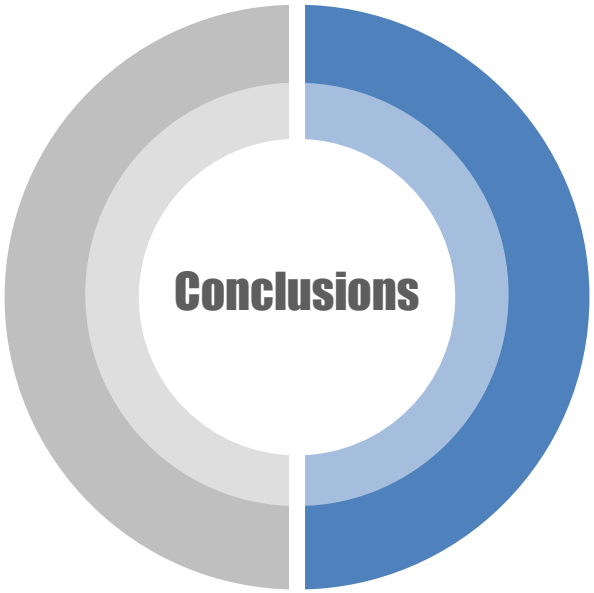
had No Evidence of Disease Activity

Two years' NEDA	Core study and extension: 40 mg		Core study: 80 mg, Extension: 40 mg		All	
	N	%	N	%	N	%
PP	7/7	100	2/4	50	9/11	**81.8**
mITT (LOCF)	8/8	100	2/5	40	10/13	**76.9**

Endpoint: Proportion of patients achieving No Evidence of Disease Activity (NEDA), defined as the absence of all the following: relapses, 12-week confirmed disability progression (CDP), new T2 lesions and T1 gadolinium-enhancing lesions

PP: Per Protocol Population; 11 patients that completed the two years.
mITT: modified Intent To Treat population, 13 patients, LOCF analysis.

Ongoing Phase II PPMS: Results



Pre-GA Depot treatment:

All enrolled subjects fulfilled the inclusion criteria of disability progression at a rate of ≥ 1 point increase / year in EDSS score prior to enrollment to the study; these subjects are considered as having rapid disease progression.

Post start of GA Depot treatment:

All enrolled subjects show either stable EDSS or improved EDSS.

API Plant

Location

Israel's designated industrial chemical park, Neot Hovav

Size

3 acres, producing Glatiramer Acetate for Depot and Generic product. Scale-up for future commercial stages on-going.

Status

GMP Approved both API (Neot Hovav) Labs (Ness Ziona) Qualified and operating for GA

QA Audit conducted by Mylan and Government of Israel, May 2019

"Preferred Enterprise" granted governmental cash grants of 20% (may increase by 4%) as a subsidy to cover capital expenditures in designated areas

Entitled to a reduced tax rate of 7.5% (compared to a 24% corporate income tax rate)

Finished Dosage Forms (FDF) Facility

Location

Har Hotzvim, Bio Park, Jerusalem

Status

Ongoing Depot production for Phase III clinical trails, scale-up for increased capacity is under-way

Agreement in place for a dedicated FDF Facility for Depot production

GMP approval by Mylan and Israeli MOH, May 2019

Expansion of facility to enable GA Depot commercial supply approved and partially funded by GOI

Experienced Management Team

EHUD MAROM
CEO & Chairman of the Board of Directors
Pharma Two B – COB, **SCM** – COB,
Teva - VP Tapi, head of the Copaxone global ops team
Makteshim (now ADAMA-ChemChina)
CEO, **Gamida Cell** - CEO

URI DANON
Executive VP
Teva – Copaxone Product Development Manager
Atox Bio – Chairman & CEO
BioCancell – President & CEO

NIR BERNSTEIN, CPA
VP Finance
Ampal Inc. - VP-Accounting & Control
PwC – Senior Manager

Dr. SHAI RUBNOV
VP R&D
NasVax - Manager QA and regulatory affairs
Peptor (DeveloGen) - Director of CMC

LAURA POPPER MD
Medical Director
Astellas Pharma – Medical Affairs Manager
Sanofi – Medical Manager, **Foamix** – Clinical Director
Bayer HealthCare – Medical Advisor &
Pharmacovigilance Country Head (PVCH)

ALEX MOGLE
VP Corporate Development
Makhteshim-Agan (ADAMA) - Head of supply chain, assistant to the CEO, Company Secretary
NICE System – BD Director DVR
Ministry of Finance

DR. RUT HAYDEN IDESES, PHD
QA Manager
Teva – API QC Manager
Dexcel – QA R&D Manager
Trima – QA Manager

NADAV BLEICH KIMELMAN, DMD, PHD,
Director Clinical Ops.
Mapi Pharma Manager, Depot Products
Depot Formulation Team Leader

Mapi Pharma

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