Maribavir (SHP620) Clinical Development Overview

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Maribavir Phase 2 Studies Data Presentation

Type of Presentation	Description	Authors Presenting Author	Congress	2016				2017			
				1	2	3	4	1	2	3	4
Oral Posters	**Study 202: Primary efficacy and safety** **Study 203: Primary efficacy and safety**	Papanicolaou G, Silveira F, Langston A, Pereira M, Avery R, Wijatyk A, Wu J, Boeckh M, Marty F, Villano S Maertens J, Cordonnier C, Jaksch P, Poire X, Wu J, Wijatyk A, Saliba F, Witzke O, Villano S	ID Week 2016				✓				
Oral Presentation	**Study 202: Primary efficacy and safety data, and pre-specified subgroup analyses by transplant type (SOT vs SCT)**	Papanicolaou G, Silveira F, Langston A, Pereira M, Avery R, Wijatyk A, Wu J, Boeckh M, Marty F, Villano S	*BMT Tandem 2017*					✓			
Oral Plenary Presentation	**Study 202: Primary efficacy and safety data, and pre-specified subgroup analyses by transplant type (SOT vs SCT)**	M R. Pereira, F P. Silveira,G Papanicolaou, A Langston, R Avery, A Wijatyk,J J. Wu, M Boeckh, F M. Marty, Villano	ATC 2017						✓		
Poster	**Study 203: Primary efficacy and safety data (encore of ID Week)**	Maertens J, Cordonnier C, Jaksch P, Poire X, Wu J, Wijatyk A, Saliba F, Witzke O, Villano S	*BMT Tandem 2017*					✓			
Oral Presentation	**Study 203: Pre-specified subgroup analyses by transplant type (SOT vs SCT)**	Maertens J, Cordonnier C, Jaksch P, Poire X, Wu J, Wijatyk A, Saliba F, Witzke O, Villano S	*EBMT 2017*					✓			

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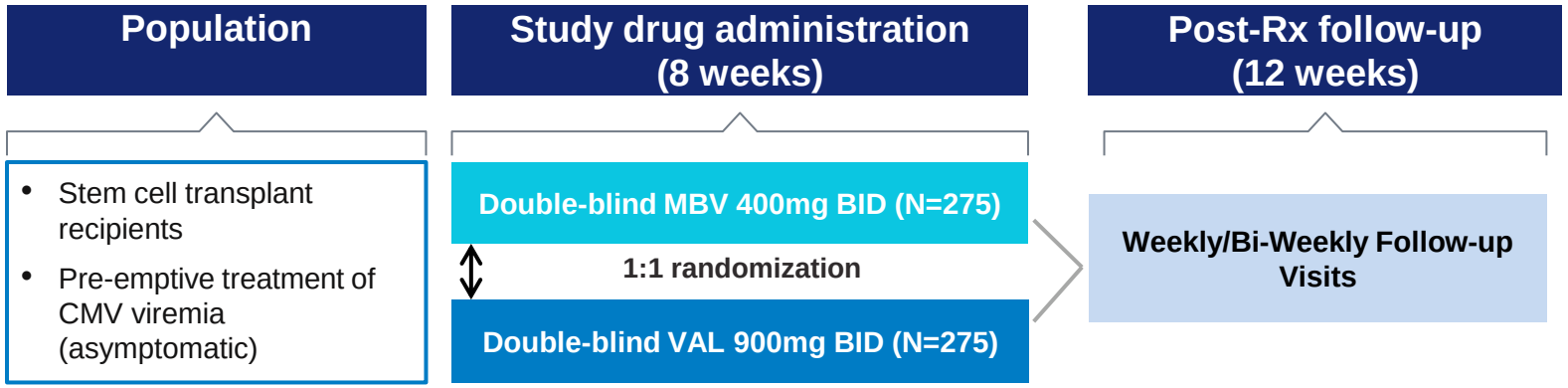
SHP620-302: Phase 3 Pre-emptive Maribavir for CMV Viremia in Stem Cell Transplant Recipients



Primary Endpoint

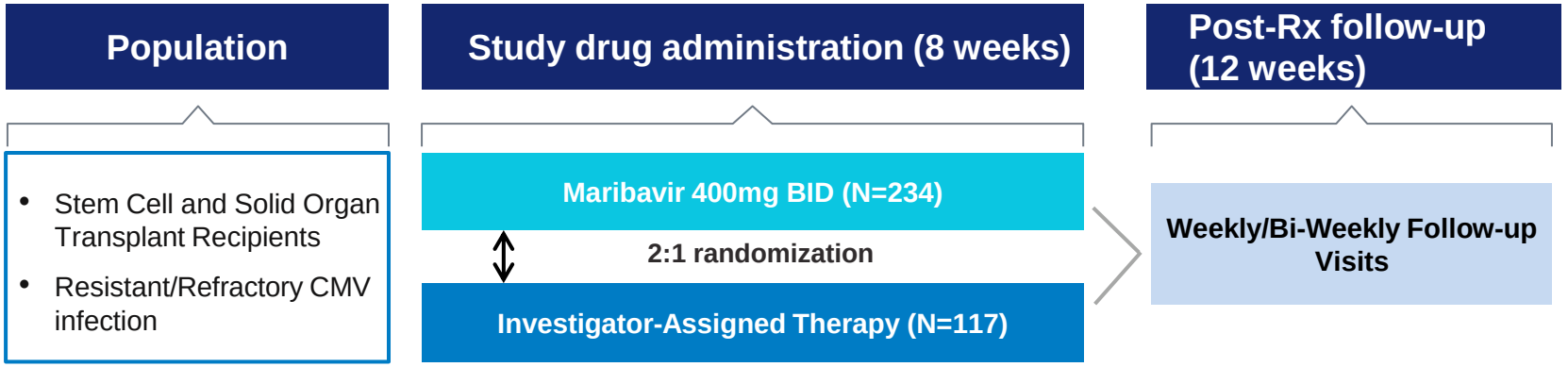
- Confirmed clearance of plasma CMV DNA (CMV viremia clearance) at the end of 8 weeks of treatment
- Key Secondary - Maintenance of CMV viremia clearance achieved after the end of 8 weeks of treatment through Study Week 16

Current Status

- Target 550 patients enrolled at sites in North America, Latin America, Europe, and Asia Pacific
- Open in North America & Europe and actively recruiting subjects
  - Web link to see active sites: www.shiretrials.com/transplant

CMV, Cytomegalovirus; MBV, Maribavir; VAL, valganciclovir
Source: clinicaltrials.gov

SHP620-303: Phase 3 Open-Label Maribavir Compared with Investigator-Assigned Treatment of Resistant/Refractory CMV Infection in Transplant Recipients



Primary Endpoint

- Confirmed clearance of plasma CMV DNA (CMV viremia clearance) at the end of 8 weeks of treatment
- Key secondary - CMV viremia clearance at the end of 8 weeks of treatment and resolution/improvement of tissue invasive CMV disease for subjects symptomatic at baseline or achievement of clearance of viremia and no symptoms of tissue invasive CMV disease for subjects asymptomatic at baseline at the end of 8 weeks of treatment, followed by maintenance of this treatment effect for an additional 8 weeks off treatment

Current Status

- Target 351 subjects enrolled at sites in North America, Europe, and Asia Pacific
- Open and actively recruiting subjects at sites in all regions
  - Web link to see active sites: www.shiretrials.com/transplant

CMV, Cytomegalovirus
Source: clinicaltrials.gov