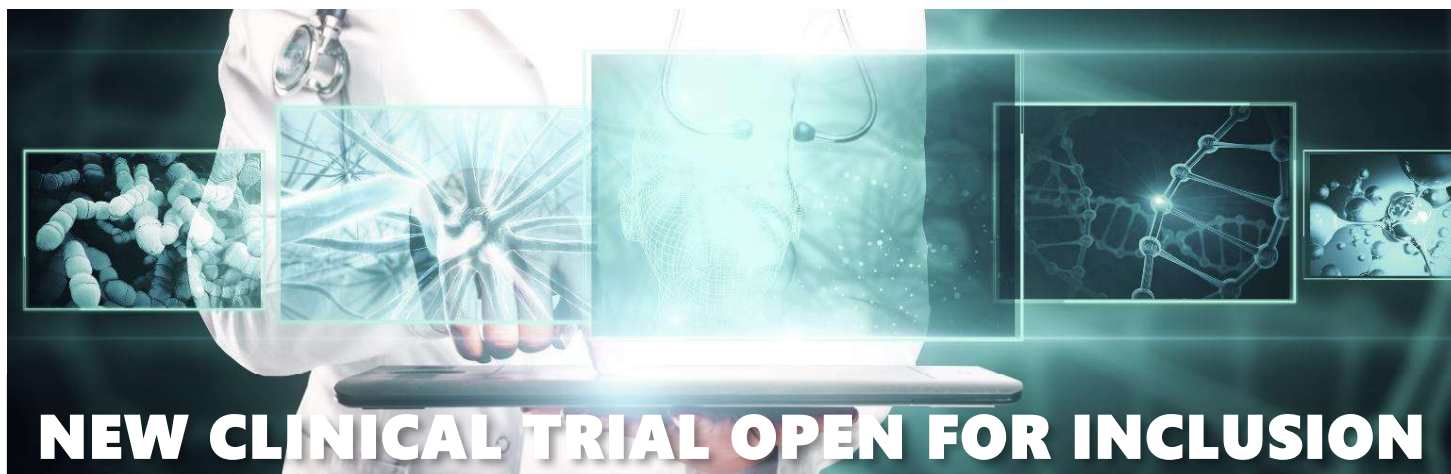




ROSETTA Lung-202: A Randomized, Double-Blind, Phase 3 Study of Punitamig Monotherapy Compared to Pembrolizumab as First-line Treatment in Participants with Locally Advanced or Metastatic Non-Small Cell Lung Cancer with PD-L1 $\geq 50\%$.

ALIAS
ROSETTA

CTO NUMBER
CTO25061BMS

SPONSOR
Bristol-Myers Squibb

Key inclusion criteria

- Advanced*/metastatic NSCLC
- (Non-)squamous
- PD-L1 $\geq 50\%$
- No prior systemic treatment for advanced disease
- Treatment for stage III disease > 6 months ago
- Measurable disease per RECIST v1.1
- ECOG 0–1

*if ineligible for surgery or definitive chemoradiotherapy

Key exclusion criteria

- Actionable driver mutation with 1L approved therapies
- Significant cardiovascular impairment (e.g. ventricular arrhythmias or major thromboembolic events)
- Clinically significant lung disease, history of ILD or pneumonitis requiring systemic steroids, current/suspected ILD or pneumonitis
- Significant risk of bleeding or history of major hemorrhagic events
- History of GI or non-GI fistula, GI perforation, or intra-abdominal abscess
- Urine protein by dipstick $\geq 2+$ and 24-h urine protein $\geq 1\text{g}/24$ hours
- Tumors with radiographic evidence of major vessel invasion/invasion of major airways or vital organs
- major cavitation posing hemorrhage risk
- Clinically significant hemoptysis

DESIGN

Randomization 1:1 ratio (n ~ 750)

- **Arm A: Punitamig** 1200 mg (if body weight < 50 kg) or 1500 mg (if body weight ≥ 50 kg) as a 60-minute IV infusion every 3 weeks (Q3W)
- **Arm B: Pembrolizumab** 200 mg as a 60-minute IV infusion every 3 weeks (Q3W)

- Dual primary endpoint: PFS (by BICR) and OS
- Maximum duration of treatment: 2 years

Stratification by:

- histology (squamous vs non-squamous)
- history/presence brain metastasis (Yes vs No)
- geographical region (Asia vs ROW)



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