Histologically or pathologically confirmed diagnosis of Stage IIIC, IIID, or IV unresectable or metastatic melanoma.

Dual primary efficacy endpoints
- ECOG PS 0 or 1 and estimated life expectancy >6 months
- Patients randomized to Arm B who receive pembrolizumab and experience confirmed ≥1 resectable lesion(s) with an estimated minimum diameter of 1.5 cm for lifileucel generation and ≥1 remaining

Adequate organ function

OS

Patients of childbearing potential or those with partners of childbearing potential must be willing to practice an appropriate form of contraception for at least 1 month prior to study entry, for the duration of treatment with lifileucel, and 2 months after the last dose of pembrolizumab.

Any form of primary or acquired immunodeficiency (eg, SCID, AIDS)

The combination of lifileucel with pembrolizumab has the potential for enhanced antitumor activity through the addition of PD-1 blockade allowing for optimal engraftment, increased cytotoxicity, and intratumoral expansion of the infused lifileucel product.

- Continued pembrolizumab therapy after lifileucel infusion is expected to perpetuate the antitumor effect
- Earlier-line treatment with lifileucel plus pembrolizumab demonstrated encouraging efficacy in patients with ICI-naive advanced melanoma in Cohort 1A of the Phase 2 IOV-COM-202 study.1-3
- Investigator-assessed ORR of 67%
- CR rate of 25%