

# NEW CLINICAL TRIAL OPEN FOR INCLUSION

## PROTOCOL TITLE

A Multicenter, Randomized, Double-blind, Phase 2/3 Study of Ficerafusp Alfa (BCA101) or Placebo in Combination with Pembrolizumab for First-Line Treatment of PD-L1-positive, Recurrent or Metastatic Head and Neck Squamous Cell Carcinoma

## ALIAS

FORTIFI-NH01

## CTO NUMBER

CTO24033BIC

## SPONSOR

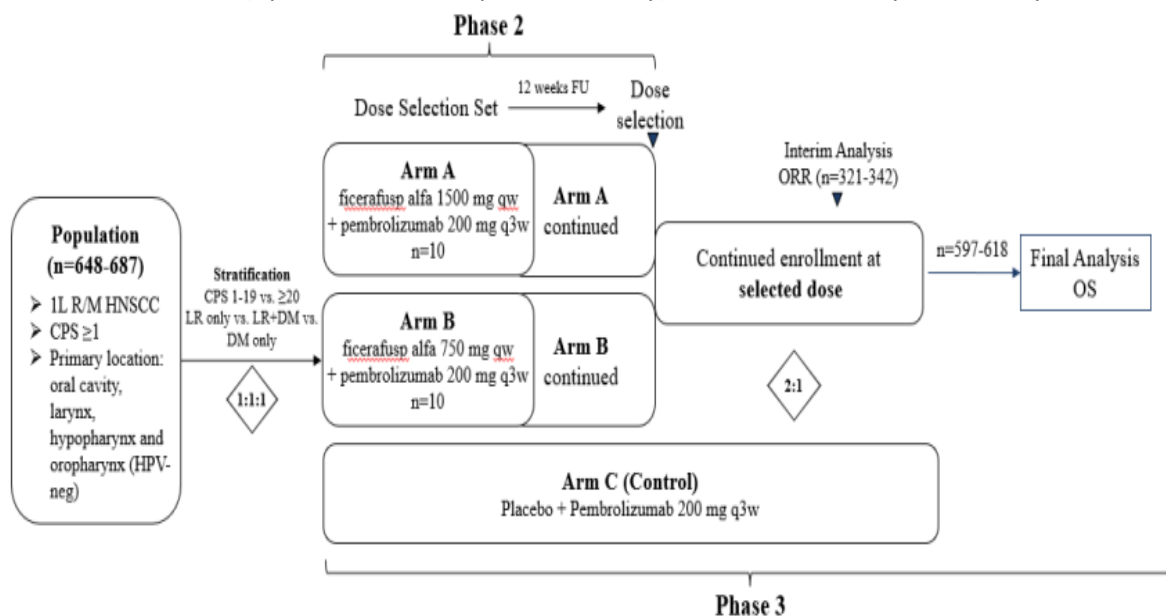
Bicara Therapeutics

## KEY INCLUSION AND EXCLUSION CRITERIA

Subject has histologically or cytologically confirmed R or M HNSCC. Eligible primary tumor locations are oral cavity, hypopharynx, larynx or oropharynx (with documented HPV-negative disease if presenting with OPSCC). Note: Primary tumor location of paranasal sinuses and nasopharynx, any histology are excluded.

No prior systemic therapy administered in the R or M setting.

Tumor PD-L1 CPS  $\geq 1$  (by PD-L1 IHC 22C3 pharmDx assay), determined locally or centrally.



## PRINCIPAL INVESTIGATOR

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