Background

• The prognosis for patients with GBM is poor.

Methods

• Study design
  - IPAX-1 is a multicenter, open-label, single-arm, dose-finding phase 2 study.
  - The study will enroll 34–44 patients and is currently recruiting at five sites in Europe. Enrollment began in July 2019.

• Key study eligibility criteria are listed in Table 1.

Figure 3. Contrast-enhanced T1 MRI (left), "F-FET-PET (middle) and "F-FET-PET/CT (right) in a patient with refractory high-grade glioma treated with "F-IPA as a single agent at a baseline and b) 10 months after therapy.

Key points

• The prognosis for patients with glioblastoma multiforme (GBM) is poor.

• Molecularly targeted radiation with 131I-IPA in combination with XRT is a novel therapeutic approach for patients with GBM.

• Preclinical research and early-stage clinical results support the potential of 131I-IPA in combination with XRT as a therapeutic approach for patients with recurrent GBM.

• The IPAX-1 study is evaluating the safety and preliminary efficacy of 131I-IPA in combination with second-line XRT in patients with recurrent GBM.

Table 1. IPAX-1 study objectives.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Description</th>
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<tbody>
<tr>
<td>Primary objectives</td>
<td>To assess the safety and tolerability of 131I-IPA + XRT</td>
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</tbody>
</table>

Secondary objectives

• To evaluate the safety of 131I-IPA; To assess the feasibility of fractionated administration of 131I-IPA; To evaluate the radiation absorbed dose to tumor from 131I-IPA; To evaluate biodistribution and absorbed doses to whole body and organs from 131I-IPA; To explore the antitumor effect of 131I-IPA + XRT combination therapy; To assess the occurrence and frequency of pseudoprogression in response to 131I-IPA + XRT combination therapy; To explore the cognitive function before, during and after therapy; To evaluate this study without permission from ASCO® and may not be reproduced through Quick Response (QR) copies of this poster obtained without permission from ASCO® and the author of this poster.

References