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The preliminary prospectus, dated January 21, 2020, is available on the SEC Web site at www.sec.gov/Archives/edgar/data/.

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Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox*

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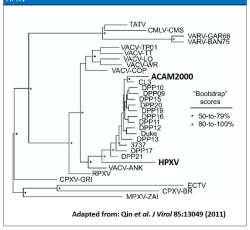
Introduction

Despite its eradication, smallpox remains a biothreat. While elements of the US military's Global Response Force service troops are vaccinated with clonal, live vaccinia virus (VACV), safety concerns limit its further use in groups like first responders. There is a need for an effective but better tolerated, single dose, live replicating smallpox vaccine. Sequence analysis of polyclonal or legacy smallpox vaccines indicate a common ancestor with horsepox virus (HPXV)[1,2], and suggest that modern VACV diverged in the core viral sequence, and in the accumulation of deletions in the left and right inverted terminal repeats (ITRs) (Figs. 1 and 2). However, it is unknown if the early HPXV-like vaccines, which protected against smallpox, exhibited different safety and efficacy profiles compared to modern VACV. To assess the tolerability and vaccine activity of scHPXV[3], four groups of macaques were vaccinated with two different doses of scHPXV, one dose of synthetic VACV (sVACV), or vehicle prior to challenge with monkeypox virus (MPXV).

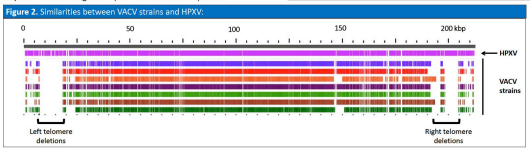
HPXV and VACVs are closely related (Fig. 1). HPXV is an environmental isolate, while VACV vaccines have a variety of telomere deletions (presumably from passage) of approximately 10.7 kB from the left ITR and approximately 5.5 kb from the right ITR (Fig. 2). Consequently, HPXV has additional genes, (relative to VACV vaccines) encoded by "complete" left and right ITRs, that are mostly involved in host immune interactions but may also serve as antigens for protective immune responses.

Figure 1. Phylogenetic relationships between VACV strains and HPXV



Adapted from: Qin *et al. J Virol* 85:13049 (2011)

Figure 2. Similarities between VACV strains and HPXV:



Experimental Procedures

scHPXV and sVACV were assembled using synthetic DNA fragments as described previously in Noyce RS et al.[3] A laboratory isolate of VACV was sequenced using Illumina sequencing technologies to obtain a complete genome sequence, including the terminal hairpin sequences and repeat regions in the inverted terminal repeats (ITRs). This sequence is very similar to VACV (strain ACAM 2000) and has been deposited in Genbank (Accession # **MN974380**). The sVACV genome sequence was also deposited into Genbank (Accession # **MN974381**).

Cynomolgus macaques (non-human primates/NHPs) (4 per group), were vaccinated *via* scarification using a bifurcated needle with $4x10^8$ ("high dose") or $5x10^5$ ("low dose") PFU of scHPXV, $8x10^8$ PFU of sVACV, or phosphate buffered saline (PBS) vehicle (Fig. 3, Table 1). Animals without takes were revaccinated*. Challenge 60 days later with $9x10^4$ PFU of MPXV (strain Zaire) *via* the intratracheal (*i.t.*) route.

Table 1. Experimental Design for scHPXV Dose-Range Finding Study in NHP.

Group	N	Vaccine (Day 0)	Vaccination Dose (PFU)*	Route of Vaccine Administration	IT Challenge Dose (Day 60)
1	4	scHPXV	$4x10^8$	Scarification	$9x10^4$ PFU
2	4	scHPXV	$5x10^5$	Scarification	$9x10^4$ PFU
3	4	sVACV	$8x10^8$	Scarification	$9x10^4$ PFU
4	4	Vehicle	N/A	Scarification	$9x10^4$ PFU

*A second vaccination by scarification (following procedures and dose volume used on Day 0) was given to four animals that did not show evidence of a take at the vaccination site by Day 7: one scHPXV animal was revaccinated with $5x10^5$ PFU scHPXV and the 3 sVACV animals were revaccinated with $2.4x10^5$ PFU sVACV. Revaccination of these four animals occurred on Day 14.

Figure 3. Treatment Timeline

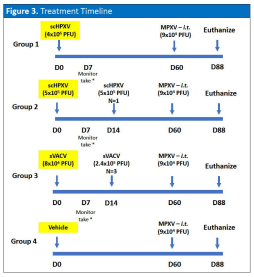


Figure 4. Representative Images of Vaccination Site on Day 7:

Group 1 scHPXV @ $4.0x10^8$ PFU | Group 2 scHPXV @ $5.0x10^5$ PFU | Group 3 sVACV @ $8.0x10^8$ PFU | Group 4 vehicle

Results

Two different doses of scHPXV vaccine were tested: 4 of 4 animals in the $4x10^8$ PFU dose, and 3 of 4 animals in the $5x10^5$ PFU dose groups exhibited a "take" at Day 7 after a single vaccination. A take is a biomarker of protective immunity. In the sVACV arm only 1 of 4 animals exhibited a take after a single vaccination. The animals that did not present a take were revaccinated on Day 14: the one scHPXV animal was revaccinated with $5x10^5$ PFU scHPXV and the 3 sVACV animals were revaccinated with $2.4x10^5$ PFU sVACV. All but one of the sVACV animals subsequently produced a take. Tolerability was comparable for scHPXV and sVACV (Figs. 5-6). After MPXV challenge (Figs. 7-9) no lesions were seen in any of the 8 animals vaccinated with scHXPV (Fig. 9). One animal in the sVACV arm died from unrelated causes, but while the 3 remaining animals all had takes, 2 still showed lesions by Day 69 (Fig. 9). Clinical signs of systemic monkeypox infections were seen in all 4 vehicle animals by Day 69. In Figs. 5-9, blue symbols are male animals and red are female.

scHPXV is Tolerated During Vaccination of Macaques

Figure 5. Weights of Macaques During Vaccination Period

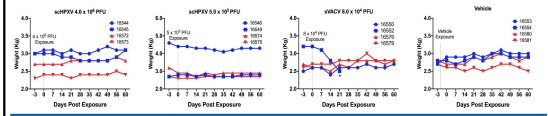
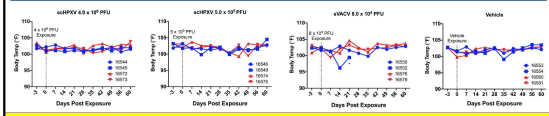


Figure 6. Body Temperature of Macaques During Vaccination Period



scHPXV Protects Macaques from Intratracheal MPXV Challenge

Figure 7. Weight Change

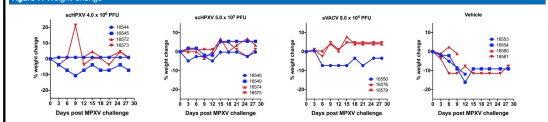


Figure 8. Change in Body Temperature

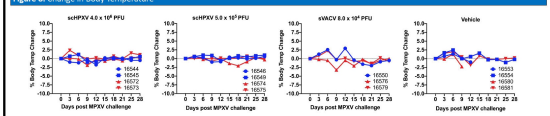
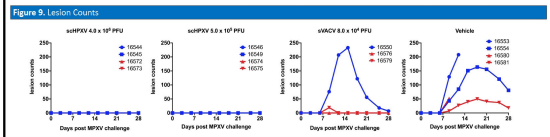


Figure 9. Lesion Counts



Conclusions

- **HPXV virus is closely related to VACV vaccines**
- **HPXV is an environmental isolate and molecular analysis indicates that HPXV has not undergone deletions** (with "complete" left and right ITRs)
- **HPXV has additional genes, relative to VACV vaccines, that could be related to host range and immune interactions**
- **Molecular analysis suggests HPXV is closer to the vaccine discovered and disseminated by Dr. Edward Jenner than modern VACV swarms and strains[4,5]** (in terms of left and right ITRs and core viral sequence)
- **Tolerability of scHPXV (high dose) is comparable to sVACV at low dose**
- **Protection of scHPXV and sVACV was comparable** (all 8 scHPXV-vaccinated animals and all 3 sVACV-vaccinated animals survived and recovered)
- **scHPXV had higher rates of "take" (4/4 high dose and 3/4 low dose animals) than sVACV (1/3 animals) after a single vaccination** ("Take" is a biomarker of protective and sterilizing immunity)
- **scHPXV induced sterilizing immunity (no lesions) in all 8 animals (4 high dose and 4 low dose), while sVACV (low dose) provided sterilizing immunity to only one of three animals**
- **scHPXV's additional genes, relative to sVACV may modulate host immune interactions and one or more may serve as antigens for protective immunity**

References Cited: [1]Schrick L et al. *N Engl J Med* (2017) 377:1491; [2]Qin *et al. J Virol* 89:1809 (2015). [3]Noyce RS et al, *PLoS One* 13:e0188453 (2018). [4]Esparza, J. et al., *Vaccine* 35:7222 (2017).

American Society of Microbiology BioThreats Conference - January 29, 2020, Arlington, VA.

*The study design was reviewed by the Institutional Animal Care and Use Committee (IACUC) at Southern Research – Funded by Tonix Pharmaceuticals

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