Journal for ImmunoTherapy of Cancer

Insights from immuno-oncology: the Society for Immunotherapy of Cancer Statement on access to IL-6-targeting therapies for COVID-19

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To cite: Ascierto PA, Fox BA, Urba WJ, *et al*. Insights from immuno-oncology: the Society for Immunotherapy of Cancer Statement on access to IL-6-targeting therapies for COVID-19. *Journal for ImmunoTherapy of Cancer* 2020;**8**:e000878. doi:10.1136/jitc-2020-000878

Accepted 01 April 2020

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Thehypoxia and profound inflammatory response associated with the pneumonitisobserved with the SARS-CoV-2 virus responsible for the recent COVID-19 pandemic has overwhelmed intensive care facilities in the epicenters of infection including Wuhan, China, Northern Italy and in the USA, the Seattle and New York City areas. The Society for Immunotherapy of Cancer (SITC) stands along with and supports our colleagues in emergency departments, intensive care units (ICUs) and inpatient wards in the global effort to overcome this unprecedented pandemic. It is becoming apparent that the 'ground glass' infiltrative appearance seen on CT scans from patients with COVID-19 with pneumonitis is reminiscent of imaging from patients with immune checkpoint inhibitor (ICI)-induced pneumonitis.[1 2] Additionally, elevated interleukin-6 (IL-6) is a hallmark inflammatory signature seen in serum of patients with severe COVID-19 acute respiratory distress.[3] Many of us have experience with the administration of immune-modulatory agents, which is why the cancer immunotherapy community is poised to contribute to the current fight against COVID-19.

One possibility is to encourage the use of IL-6 or IL-6-receptor (IL-6R) blocking antibodies like tocilizumab (Actemra™, Roche-Genentech), sarilumab (Kevzara™, Regeneron) and siltuximab (Sylvant™, EUSA Pharma) that are Food and Drug Administration (FDA) approved for various conditions, including rheumatological disease and the lymphoproliferative disorder Castleman's syndrome. These agents could be used on easily and immediately available compassionate use protocols that could be approved on an emergency basis by all institutional review boards (IRBs) around the world for critically ill patients with COVID-19-induced hypoxia. Tocilizumab also is already FDA approved to manage cytokine release syndrome (CRS) in patients receiving chimeric antigen receptor T cell therapy.[4 5] In addition, tocilizumab has been shown to reduce toxicity in patients treated with ICIs who were steroid refractory,[6] and has been added to the ICI agents ipilimumab and nivolumab in an ongoing US phase II study (NCT03999749) to ameliorate immune-related toxicity. In Castleman's disease, a lymphoproliferative disorder caused by Kaposi's Sarcoma Herpesvirus, a pathogen that produces viral IL-6, tocilizumab has been shown to reduce viral loads.[7] Tocilizumab is also being explored as a potential supportive care measure for the management of CRS in patients with cancer treated with a number of CD3-based bispecific molecules. Now, data from the frontlines of the pandemic indicates that the agent may offer lifesaving benefit for COVID-19 patients with respiratory distress.

Emerging evidence suggests that high levels of C reactive protein (CRP) and IL-6 are observed in patients infected with COVID-19.[1 8] Anecdotal experience on the use of tocilizumab at doses comparable to those used for the management of CRS from investigators in Italy[9] and from China[10] has reported rapid improvement in both intubated and non-intubated patients. In these reports, expeditious administration of anti-IL-6R therapy for patients in acute respiratory distress has been critical. A recent study protocol to evaluate the efficacy of tocilizumab in COVID-19-induced pneumonitis accrued over 300 patients worldwide in less than 24 hours. Additionally, Genentech will also provide 10 000 vials of tocilizumab to the US Strategic National Stockpile.[11] Tocilizumab was also approved in China in March 2020, for the treatment of patients with COVID-19 with serious lung damage and elevated IL-6. Sponsors, investigators and regulators have moved with unprecedented speed and collaboration to initiate protocols to formally study the safety and efficacy of antiviral agents and vaccines, as well as various anti-IL-6 antibodies in patients with COVID-19. In the USA, a trial of sarilumab in the COVID-19 setting is ongoing.[12]

Although randomized data definitively showing that IL-6R blockade benefits patients with COVID-19-induced pneumonitis are currently lacking, we propose that an effort should be made to maximize the availability of anti-IL-6 agents, includingtocilizumab and sarilumab for use on a compassionate basis to critically illhospitalized SARS-CoV-2-infected patients during this extraordinary situation. In addition, consideration should be given to focus efforts on rapidly expanding the ability of clinicians and clinical investigators to access investigational anti-IL-6 agents, in particular for those agents where phase 1 and/or phase 2 studies have been completed, and acceptable safety has been demonstrated. Even if the primary impact of a single dose of these drugs is to accelerate recovery and get patients off ventilator support and out of the ICU more rapidly, this could significantly decompress our severely overburdened healthcare systems. We suggest that straightforward parameters including complete blood counts and differentials, serum lactate dehydrogenase (LDH), ferritin, CRP and IL-6 be recorded in treated patients, that serum be retained for future analyses, and simple clinical parameters be assessed including time in ICU, days of hospitalization and pulmonary parameters, including forced expiratory volume in 1 s (for non-intubated patients), fractional inspired oxygen (FiO_2), arterial oxygen tension/FiO_2 ratio and type of oxygen supplementation need be recorded pre-anti-IL-6R and post-anti-IL-6R therapy. A simple compassionate use protocol could be assembled from existing templates, and all efforts should be made for emergency approval of the use of IL-6R blocking antibodies by local IRBs within 24 hours of the request being made. Additionally, consideration should be given by pharma and biotech to redirect the use of facilities and increase personnel involved in drug manufacturing and those serving as liaisons to the frontlines to facilitate drug availability. Extraordinary times call for extraordinary measures, and SITC calls on all involved, including pharmaceutical sponsors, health authorities and IRBs, to continue to move swiftly and creatively to remove barriers and increase access to agents like anti-IL-6R drugs that may improve our care for COVID-19 pneumonitis.

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Correction notice Since the online publication of this article, the authors have noticed errors in author names, affiliations, the competing interests section and also the main text.

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Acknowledgements The authors thank the clinicians working tirelessly on the frontlines of the COVID-19 pandemic. The authors also acknowledge SITC staff for their contributions including Sam Million Weaver, PhD for medical writing and editorial support and Angela Kilbert for project management and assistance. Additionally, the authors wish to thank the society for supporting the manuscript development.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests PAA: Consultant/Advisory Role: Bristol-Myers Squibb, Roche-Genentech, Merck Sharp & Dohme, Array, Novartis, Merck Serono, Pierre Fabre, Incyte, NewLink Genetics, Genmab, Medimmune, AstraZeneca, Syndax, SunPharma,

Sanofi, Idera, Ultimovacs, Sandoz, Immunocore, 4SC, Alkermes, Italfarmaco, Nektar; Research Funds: Bristol-Myers Squibb, Roche-Genentech, Array; Travel support: MSD; BAF: Cofounder/Stock: UbiVac; Consulting/Research Support: Macrogenics, OncoSec, Shimadzu, Viralytics (Merck); Consulting (Il-ON)/Research Support: Bristol-Myers Squibb; Consulting/Stock: PrimeVax; Research Support: NanoString, Quanterix; SAB: Argos, Bayer, CellDex, UltiVue; SAB/Institutional Research Support: AstraZeneca (MedImmunne); SAB/Research Support: Akoya BioScience (Perkin Elmer), Definiens; WJU: Advisory Board: MedImmune, Bristol-MyerS Squibb; Research Support/Contracted Work: Bristol-Myers Squibb; Research Support: MedImmune; ACA: Consulting Fees: Tizona Therapeutics, Compass Therapeutics, Zumutor Biologics; Ownership Interest: VBI vaccines; Scientific Advisory Board: Compass Therapeutics, Zumutor Biologics Inc, Tizona Therapeutics; MBA: Advisory Board: Bristol-Myers Squibb, Merck, Novartis, Arrowhead, Pfizer, Galactone, Werewolf, Fathom; Consultant: Bristol-Myers Squibb, Novartis, Genetch-Roche, Exelixis, Eisai, Aveo, Array, AstraZeneca, Idera, Aduro, ImmunoCore, Boehringer-Ingelheim, Lion, Newlink, Surface, Alexion, Acceleron, Lynx, Cote; Research Support: Bristol-Myers Squibb; Stock Options: Werewolf; JRB: Advisory Board: Amgen, BMS Celgene, Eli Lilly; Genentech, Merck, Syndax; Consulting: BMS, Genentech, Eli Lilly, Merck; Research/Grant Funding: MedImmune/AstraZeneca, Merck; LHB: Consulting Fees: StemImmune/Calidi Scientific and Medical Advisory Board, NextCure; Scientific Advisory Board: Replimmune, Western Oncolytics, Torque Therapeutics, Khloris, Pyxis, Cytomix, Roche-Genentech Biomarkers Roundtable; AC: Consulting Fees: Refuge Bio, Arch Oncology, Qognit, Nanostring; Salary: ESSA Pharma; DSC: Ownership Interest: IGM Biosciences; Salary: IGM Biosciences; CGD: Consultant Fees: Agenus, AstraZeneca, Dendreon, Eli Lilly, Janssen, Merck, Pierre Fabre, Roche/Genetech; Ownership Interests: Compugen, Harpoon, Kleo; Patents/Royalties: AstraZeneca, Bristol-Myers Squibb, Janssen; Research Funding: Aduro Biotech, Bristol-Myers Squibb, Janssen; LAE: Contracted Research: Aduro Biotech, AstraZeneca, Bristol-Myers Squibb, Corvus, EMD Serono, Genentech, F Hoffman La Roche, Maxcyte, Merck, Tempest; Consulting Fees: Genentech, F Hoffman La Roche, Syndax, Eli Lilly, AbbVie, Amgen, AstraZeneca, Bayer, Bristol-Myers Squibb, Celgene, Chugai, Genentech, F Hoffman La Roche, Gritstone, Medimmune, Macrogenics, Novartis, Peregrine, Replimune, Silverback, Vaccinex; IP Rights: Aduro Biotech; Royalty: Elsevier; Salary: University of Pittsburgh, UPMC UPP; Grants from non-industry entities: HeritX Incorporated, NSABP Foundation, Translational Breast Cancer Research Consortium, Breast Cancer Research Foundation, National Cancer Institute, Department of Defense, Johns Hopkins University, University of California San Francisco; TDG: Consulting Fees: DCPrime BV, Macrophage Pharma, Partner Therapeutics; Contracted Research: Idera Pharmaceuticals, Macrophage Parma; IP Rights/Patents: The use of cytostatics for the accelerated differentiation of DC WO2009019320-A2; WO2009019320-A3; AU2008285598-A1; EP2281030-A2; CA2724018-A1; US2011117051-A1. US8,470,789B2 of DC prime BV, Immunoglobulins binding human VÎ³9VÎ'2 T cell receptors, CD1d domain antibodies targeting CD1d P32016NL00 EP16715360.0-1412, LAVA Tx BV; Ownership Interest: LAVA Therapeutics BV (stocks), Salary: Vrije Universiteit Medical Center Amsterdam; TFG: Consultant/Advisory Board: Roche-Genentech, Merck, Abbvie, Bayer, Jounce, Aduro, Fog Pharma, Adaptimmune, FivePrime, Sanofi; Research Support: Roche-Genentech, Bristol-Myers Squibb, Merck, Incyte, Seattle Genetics, Celldex, Ono, Evelo, Bayer, Adure; IP/Licensing: Aduro, Evelo; Cofounder/shareholder: Jounce; FSH: Advisory Board: Aduro, Amgen, 7 Hills Pharma, Compass Therapeutics, Takeda, Rheos, Surface, Verastem; Advisory Board/Equity: Poinyr; Consulting Fees: Genetech/Roche, Bayer, Bristol-Myers Squibb, EMD Serono, Kairos, Merck, Partners Therapeutics, Sanofi, Pfizer, Pieris Pharmaceutical; Scientific Advisory Board/Equity: Apricity, Torque, Bicara; Grant/Royalties to Institution: Bristol-Myers Squibb, Novartis; PH: Consulting Fees: Immatics, Sanofi, Dragonfly, GlaxoSmithKline; DK: Scientific Advisory Board, Celsius Therapeutics, Hookipa Pharma; HLK: Salary: Immuneering Corporation; MTL: Consulting Fees: Torque, Repertone, Checkmate, Salary: Iovance; FMM: Consulting Fees: Calidi Biotechnologies, Salary: Refuge Biotechnologies; KAM: Consulting Fees: ImaginAb SAB, Iovance DMC, Neoleukin ad board (Non CME Services, <10k/year from each entity); MVM: Consulting/Advising: Adaptimmune Therapeutics, Agentus, Agenus inc, Allogene, Arcellx, Bluebird Bio, GSK, Incysus, Kite Pharma, Novartis; Scientific Advisory Boards: Century Therapeutics, CRISPR Therapeutics. 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Patient consent for publication Not required.

Provenance and peer review Commissioned; externally peer reviewed.

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Correction: *Insights from immuno-oncology: the Society for Immunotherapy of Cancer Statement on access to IL-6-targeting therapies for COVID-19*

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Since the online publication of this article, the authors have noticed the following errors:

1) The following authors were missing the middle initial in their name; Bernard A Fox, Walter J Urba, Julie R Brahmer, Daniel S Chen, Tanja D de Gruijl, F Stephen Hodi Jr, Howard L Kaufman, Michael T Lotze, Kim M Margolin, Francesco M Marincola. The author name Jon M Wigginton was also spelt incorrectly as Jon M Wiggington. The author list is shown below and has been updated in the article.

Paolo Antonio Ascierto,[1] Bernard A Fox,[2] Walter J Urba,[2] Ana Carrizosa Anderson,[3] Michael B Atkins,[4] Ernest C Borden,[5] Julie R Brahmer,[6] Lisa H Butterfield,[7] Alessandra Cesano,[8] Daniel S Chen,[9] Tanja D de Gruijl,[10] Robert O Dillman,[11] Charles G Drake,[12] Leisha A Emens,[13] Thomas F Gajewski,[14] James L Gulley,[15] F Stephen Hodi Jr,[16] Patrick Hwu,[17] David Kaufman,[18] Howard L Kaufman,[19] Michael T Lotze,[20] Douglas G McNeel,[21] Kim A Margolin,[22] Francesco M Marincola,[23] Michael J Mastrangelo,[24] Marcela V Maus,[25] David R Parkinson,[26] Pedro J Romero,[27] Paul M Sondel,[28] Stefani Spranger,[29] Mario Sznol,[30] George J Weiner,[31] Jon M Wigginton,[32] Jeffrey S Weber[33]

2) Affiliations 1, 2, 3, 4, 5, 11, 14, 15, 16, 20, 21, 22, 26, 28 were incorrect and affiliations 8, 32, 34 have been removed. The updated affiliation list is shown below and has been updated in the article.

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3) In the main text,

- The sentence 'The hypoxia and profound inflammatory response associated with the pneumonitis observed with the severe acute respiratory virus coronavirus-2 SARS-COV-2 virus…' now reads 'The hypoxia and profound inflammatory response associated with the pneumonitis observed with the SARS-CoV-2 virus…'
- The sentence 'One possibility is to encourage the use of IL-6 or IL-6-receptor (IL-6R) blocking antibodies like tocilizumab (Actemra, Roche-Genentech), sarilumab (Kevzara, Regeneron) and siltuximab (Sylvant, EUSA Pharma)…' now reads 'One possibility is to encourage the use of IL-6 or IL-6-receptor (IL-6R) blocking antibodies like tocilizumab (Actemra™, Roche-Genentech), sarilumab (Kevzara™, Regeneron) and siltuximab (Sylvant™, EUSA Pharma)…'
- The sentence '…including tocilizumab and sarilumab for use on a compassionate basis to critically ill hospitalized COVID-19-infected patients during this extraordinary situation' now reads '…including tocilizumab and sarilumab for use on a compassionate basis to critically ill hospitalized SARS-CoV-2-infected patients during this extraordinary situation'

4) To acknowledge medical writing support, the acknowledgment section has been updated to read:

'The authors thank the clinicians working tirelessly on the frontlines of the COVID-19 pandemic. The authors also acknowledge SITC staff for their contributions including Sam Million Weaver, PhD for medical writing and editorial support and Angela Kilbert for project management and assistance. Additionally, the authors wish to thank the society for supporting the manuscript development.'

5) In the competing interests section:

- Bristol-Myers Squibb was spelt incorrectly as 'Bristol-Myer Squibb' and 'Bristol-Myers-Squibb'
- The initials for authors BF, JB, ACA, DC, TdG. HK, ML, FM, KM now read BAF, JRB, AC, DSC, TDG, HLK, MTL, FMM, KAM

J Immunother Cancer 2020;**13**:e000878corr1. doi:10.1136/jitc-2020-000878corr1

Amendment to *'Correction: Insights from immuno-oncology: the Society for Immunotherapy of Cancer Statement on access to IL-6-targeting therapies for COVID-19'*

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This correction notice incorrectly stated that Kim Margolin's middle initial was 'M' instead of 'A' in the first paragraph.

The first paragraph should instead read, 'The following authors were missing the middle initials in their names; Bernard A Fox, Walter J Urba, Julie R Brahmer, Daniel S Chen, Tanja D de Gruijl, F Stephen Hodi Jr, Howard L Kaufman, Michael T Lotze, Kim A Margolin, Francesco M Marincola. The author name Jon M Wigginton was also spelt incorrectly as Jon M Wiggington. The author list is shown below and has been updated in the article.'

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J Immunother Cancer 2020;**8**:e000878corr1Amendment. doi:10.1136/jitc-2020-000878corr1Amendment